DLP Cardiac Partners

Duke LifePoint Healthcare

August 17, 2012

Via Hand Delivery and E-Mail

Dr. Thomas J. Pulliam
State Health Coordinating Council

Dr. Christopher G. Ullrich, Chair
SHCC Technology and Equipment Committee

North Carolina Division of Health Service Regulation
Medical Facilities Planning Section
809 Ruggles Drive
Raleigh, NC 27603

Re: Comments Opposing Johnston Health Petition to Repeal Cardiac Cath Rule

Dear Dr. Pulliam and Dr. Ullrich:

I am writing to submit DLP Cardiac Partners, LLC's enclosed comments in opposition to the August 1 Petition submitted by Johnston Health to eliminate the regulatory restriction on the provision of therapeutic cardiac catheterization (PCI) procedures in facilities without open heart surgery. DLP Cardiac Partners, LLC (DLPCP) appreciates the opportunity to comment regarding Johnston Health's Petition and this important issue. DLPCP is part of Duke LifePoint Healthcare, a joint venture of Duke University Health System and LifePoint Hospitals. In North Carolina, DLPCP manages six cardiac catheterization labs at five community hospitals, and operates mobile cardiac catheterization units around the State.

For the reasons detailed in the enclosed comments, DLPCP believes the oversimplified and rushed approach to this issue proposed by Johnston Health is not substantiated, appropriate or lawful. There are numerous health and safety and public policy factors involved in determining how best to address the question of whether, and under what conditions, PCI should be permitted in facilities without the available back-up of open heart surgery. And those factors deserve careful and thorough study, comment, and hearing before any decision is made by the SHCC on this issue. It simply would not make sense to lift the current restriction limiting the provision of PCI to facilities with open heart surgery, and then subsequently develop the conditions which must apply to ensure that PCI services are safely and properly provided in facilities without open heart surgery. North Carolinians deserve a smarter and more deliberate approach to this aspect of cardiac care.

If the SHCC is inclined to consider changing or eliminating restrictions on the provision of PCI in facilities without open heart surgery, DLPCP respectfully urges the SHCC to consider establishing a task force to study and address these issues in the regular spring phase of the 2013 planning year. There is ample cardiac catheterization capacity throughout the State to allow careful consideration and review of these serious issues within the normal course of the SHCC's health planning process.

Thank you in advance for your attention to these important issues.

3700 Arco Corporate Drive, Suite 450, Charlotte, NC 28273 704-714-8858

DLP Cardiac Partners

Duke LifePoint Healthcare

With best regards, I am

Sincerely,

Todd Williamson
Executive Director

3700 Arco Corporate Drive, Suite 450, Charlotte, NC 28273 704-714-8858

Comments Opposing Johnston Health's Petition for New Cardiac Catheterization Rule

2013 State Medical Facilities Plan

August 17, 2012

Submitted By:

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Contact Information:

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DLP Cardiac Partners, LLC (DLPCP) submits the following comments in opposition to the petition for a new cardiac catheterization SMFP provision (Petition) submitted by Johnston Health on August 1. DLPCP opposes Johnston Health's Petition for a number of reasons including:

- The Petition is an inappropriate and unreasonable attempt to sidestep North Carolina's rulemaking procedure, and repeal an existing regulation governing the provision of therapeutic cardiac catheterization procedures (PCI) in our State by virtue of an eleventh-hour amendment to the SMFP.

- The Petition greatly oversimplifies the numerous clinical and public policy factors and concerns inherent in the question of providing PCI in a facility without open heart surgery capabilities, presenting an incomplete and misleading picture of the issue.

- The issues raised in the Petition involve important public policy and health and safety issues regarding PCI with statewide impact, which deserve full and informed study, hearing and comment from interested parties. The appropriate time to consider such issues, should the SHCC elect to do so, would be during the Spring of the next planning year, if so petitioned.

- There is no pending crisis of cardiac catheterization access which would warrant granting Johnston Health's novel Petition and subverting our State's well-established rulemaking process for amending permanent regulations.

- Grandfathering existing providers of health care services when the law governing a particular type of facility or service changes, is a legally necessary, common, and generally accepted principle and practice, which does not warrant the unusual and unprecedented action sought in the Petition.

- Allowing the Petition would set bad and dangerous precedent for health care providers and interested parties who disagree with other certificate of need or licensure rules.

Background

Johnston Health's Petition essentially asks the State Health Coordinating Council (SHCC) to direct the CON Section to implement a temporary rule which would repeal an existing permanent rule restricting the performance of PCI in facilities that do not offer open heart surgery services. Johnston Health seeks to accomplish this "adjustment" by inserting the following single sentence regarding cardiac catheterization in the 2013 SMFP:

> "It is further determined that fixed cardiac catheterization equipment shall not be limited to diagnostic procedures only"

In other words, Johnston Health is seeking to eliminate the permanent regulation limiting the provision of PCI services to hospitals with on-site cardiac surgery.

The Petition indicates Johnston Health is seeking this adjustment for the purpose of allowing "a change in the Certificate of Need rules that would allow for the provision of interventional cardiac catheterization services in Johnston County." The "adjustment" requested by Johnston Health is to repeal a provision of a CON rule governing cardiac cath equipment which applies statewide and has been in place for many years. The Petition is not limited to Johnston Health or Johnston County. The additional SMFP provision proposed by Johnston Health would impact providers of cardiac catheterization services and the patients they serve across North Carolina.

Under current North Carolina law, in order to obtain CON approval for the performance of therapeutic cardiac cath procedures on fixed equipment an applicant must be able to demonstrate that open heart surgery services are provided in the same facility. 10A NCAC 14C.1604(a) ("Cardiac Cath Support Rule"). There are a number of providers who were approved to perform cardiac cath services before this current law was adopted, which have grandfathered status and are able to provide therapeutic cardiac cath procedures without open heart surgery. These circumstances have existed since 1993 when North Carolina law on this issue changed.

Currently, there are 11 sites in North Carolina that can perform PCI without open heart surgery due to the grandfathered status of the provider having performed such services prior to the 1993 change in the CON Law. Several of the grandfathered cardiac cath providers are sites affiliated with DLPCP. There are approximately 20 cardiac cath sites in the State that currently provide only diagnostic cath services, including Johnston Health.

Johnston Health has a cardiac cath lab, but does not offer open heart surgery and is not a grandfathered provider, and therefore, it currently is limited to diagnostic cardiac cath procedures. One of the primary bases for Johnston Health's Petition is that grandfathered cardiac cath providers have an unfair advantage because they are able to perform therapeutic procedures without the availability of open heart surgery in the same facility.

DLP Cardiac Partners, LLC is part of Duke LifePoint Healthcare, a joint venture of Duke University Health System, a leading academic health system in our State as well as the U.S., and LifePoint Hospitals, a leading hospital system with 56 hospital campuses across the U.S. DLPCP has extensive experience throughout the U.S. in successfully developing and managing cardiac cath labs. In North Carolina, DLPCP manages six cardiac catheterization labs at five community hospitals, and operates mobile cardiac catheterization units around the State.

1. Improper Attempt to Bypass Rulemaking

Johnston Health's Petition seeks to bypass North Carolina's rulemaking process, and instead accomplish a significant regulatory change under the guise of an SMFP "adjustment." The restriction on PCI services to which Johnston Health objects does not appear in, or arise from, the SMFP or any methodologies in the SMFP. This restriction is established by our State's CON regulations governing cardiac cath proposals. *See* 10A NCAC 14C.1604(a). Johnston Health's Petition is a request to change a permanent rule, and therefore, should be made through the permanent rulemaking process at the Rules Review Commission, not the SHCC's development of the SMFP. The SMFP is a health planning resource and tool which is not intended to be, and should not be permitted to be misused as, a workaround for interested parties wishing to change existing State regulations. The temporary rulemaking specifically provided for in connection with the SMFP under N.C. Gen. Stat. § 150B-21.1(a)(6), is allowed only to give effect to annual changes in the Plan that would otherwise be moot if they could not be implemented more quickly.

The North Carolina CON Section is authorized to adopt and implement binding and substantive regulations only through properly promulgated rules. *See* N.C. Gen. Stat. §§ 131E-177 (designating DHHS as State Health Planning and Development Agency, and empowering it to "adopt rules pursuant to Chapter 150B of the General Statutes, to carry out the purposes and provisions of this Article [the CON Law]"), and 131E-183(b) (authorizing DHHS to adopt rules for review of particular types of applications to be used in addition to statutory criteria). In regulatory reforms adopted in 2011, the General Assembly underscored the importance of agencies following and abiding by the State's rulemaking process by adding the following provision at the outset of the rulemaking article in Chapter 150B: "An agency shall not seek to implement or enforce against any person a policy, guideline, or other nonbinding interpretive statement that meets the definition of a rule contained in G.S. 150B-2(8a) *if the policy, guideline, or other nonbinding interpretive statement has not been adopted as a rule in accordance with this Article*." N.C. Sess. Law 2011-398, § 1.

Permanent rulemaking in our State is a comprehensive and detail-intensive process for good reason -- in addressing significant public policy and public health and safety issues, it is important to provide a full and informed hearing and comment process which allows an adequate opportunity for input from affected health care providers and other interested parties across the State. The clinical and public policy questions presented in Johnston Health's Petition deserve careful and informed study, consideration, hearing, and vetting, not a backdoor approach. Johnston Health touts its Petition as the "most expeditious way" to achieve its desired repeal of the Cardiac Cath Support Rule. However, in areas involving important public health and safety issues such as the question of PCI at facilities without open heart surgery, speed is not the key to the best and most appropriate regulation and public policy.

Contrary to Johnston Health's assertions in its Petition, the question of providing therapeutic cardiac cath services without the available back-up of open heart surgery is specifically addressed under North Carolina law in the Cardiac Cath Support Rule, and the answer is clearly no. The only exception to this current law are grandfathered providers who were approved to provide such services before the current Cardiac Cath Support Rule was adopted. Johnston Health's suggested approach to changing our State's law on this issue by virtue of a quick and easy SMFP adjustment is unsubstantiated, unprecedented and unwise.

Johnston Health's own Petition and the materials attached to it, demonstrate that the question of providing PCI in facilities without open heart surgery is a complex issue involving numerous clinical and public policy factors. Accordingly, the simplistic and unnecessarily rushed approach to this issue being pushed by Johnston Health should be rejected in favor of a more thorough and informed examination of the issue.

2. Oversimplification of PCI in Facilities Without Open Heart Surgery

In an attempt to make its case for repealing the Cardiac Cath Support Rule, Johnston Health has oversimplified the issue of providing PCI in facilities where open heart surgery, conveniently ignoring factors which indicate the question is not as clear-cut as the Petition suggests. While the Petition mentions several States which permit PCI at hospitals where open heart surgery is not available, it is clear from Johnston Health's own description of the law in these other states that they have not given carte blanche to facilities to allow PCI without on-site cardiac surgery. Even if these other States may have adjusted their respective approaches to PCI at hospitals without open heart surgery, it is highly doubtful that they did so without examining the issue carefully and thoroughly beforehand.

By way of example, a closer look at the regulation of PCI in Pennsylvania and Maryland confirms that the provision of PCI in hospitals without open heart surgery is not generally permitted, but rather is closely regulated. In Pennsylvania, only emergency PCI services are permitted at hospitals with no open heart surgery capacity. *See* 28 Pa. Code §§ 138.15 and 138.17; Access to Advanced Cardiac Care from Pennsylvania Department of Health website, copies of which are attached hereto as Appendix 1.

Maryland only allows PCI in hospitals that do not offer open heart surgery pursuant to a highly regulated research waiver program as part of a study to assess the safety and efficacy of providing PCI services without on-site cardiac surgery. Under Maryland's waiver program, hospitals were given a one-time opportunity to obtain a research waiver by demonstrating they met the criteria for the program, and are required to comply with detailed regulations governing the waiver. Maryland's waiver program is all part of an study of providing PCI services for certain patient groups without on-site cardiac care to help the State determine how best to regulate this area. *See* COMAR 10.24.05.02, .04, .06 and .07 copies of which are attached hereto as Appendix 2. The waiver program in Maryland was developed only after the CON Task Force of the Maryland Health Care Commission studied the issue and designed the research project over a period of several years. *See* Maryland CON Task Force Report dated October 1, 2008, an excerpted copy of which is attached hereto in Appendix 2.

Likewise, the 2011 guidelines from the American College of Cardiology and 2012 policy guidance from the American Heart Association cited by Johnston Health which indicate that PCI without open heart surgery may be appropriate under certain circumstances, are dependent upon a number of factors including facility, personnel and physician requirements. These guidelines make clear that the question of whether PCI can safely be provided without available open heart surgery is not a simple one. None of the factors included in the ACC and AHA guidelines are addressed substantively in Johnston Health's Petition, except for a general suggestion that they could be handled through licensure rules. Although Johnston Health cites the ACC and AHA guidelines as support for its petition, it does not propose that those guidelines be incorporated into the regulations. Instead, it simply asks that the SHCC direct the initiation of rulemaking to lift the restriction on PCI without the addition of any substitute requirements. Granting this request would clear the way for every cardiac cath provider in the State to begin providing PCI without the necessary planning and safeguards. Likewise, each provider without on-site cardiac surgery would be free to establish its own internal protocol and standards for providing PCI services.

3. Untimely Petition for Change in Policy with Statewide Impact

Johnston Health's Petition seeks to change well-established law and public policy governing the provision of PCI across North Carolina, through the insertion of a one-sentence provision in the 2013 SMFP. To the extent any such proposal would ever be appropriate, which DLPCP believes is highly questionable, the appropriate time for such a petition expired five months ago with the March 7 deadline for petitions recommending changes with statewide effect. See 2012 SFMP, p. 9. It has long been practice of the State Health Coordinating Council to consider proposed changes which would have a statewide impact early in the Spring, in order to allow adequate time to fully consider such issues and determine whether and how best to address them in the next SMFP. Health care providers and other stakeholders generally are well aware of this aspect of the SHCC's planning schedule for the next SMFP. In any event, Johnston Health and all other stakeholders had ample notice of the March 7 deadline for petitions suggesting changes to the

2013 SMFP with statewide effect, given that this date was included in the approved 2012 SMFP which was published in early January 2012 as well as prior drafts of the proposed 2012 SMFP. Like all other stakeholders, Johnston Health had the opportunity to prepare and submit a petition regarding the PCI "adjustment" it now seeks during the Spring of 2012. Johnston Health's August 1 Petition is devoid of any explanation regarding why it did not do so. Having failed to submit a timely recommendation regarding the PCI issues with statewide impact which are the subject of its Petition, it is unreasonable and inappropriate for Johnston Health to ask the SHCC at the eleventh hour of the planning year to rush to judgment on issues which deserve full and careful study, comment and consideration.

In addition, the change in the law which Johnston Health seeks to accomplish through the 2013 SMFP is not specific to a particular provider or geographic area, and therefore, is not an appropriate issue to address in the summer cycle of petitions. The SMFP provides that "People who believe that unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies may submit a written petition requesting an adjustment be made to the need determination given in the North Carolina Proposed State Medical Facilities Plan" in the summer petition cycle. However, Johnston Health's requested "adjustment" to the SMFP is a change in North Carolina law which would have statewide impact on all cardiac catheterization providers.

Even in the Spring petition review cycle, petitions are submitted to address the SMFP's policies and methodologies governing the development of new regulated assets in the state. Johnston itself expressly states, "However, this petition does not request a change to the methodology or any other policies in the SMFP; therefore, it is not any more appropriate for filing during [the spring] timeframe." The fact that the Petition seeks a permanent change to the Cardiac Cath Support Rule, and does not involve any SMFP policy or methodology, again suggests that Johnston Health should follow the rulemaking process rather than try to force its request under the guise of an SMFP need adjustment petition.

4. No Crisis of Cardiac Cath Access

There is no current or pending crisis of cardiac cath access that warrants sidestepping the rulemaking process to repeal the Cardiac Cath Support Rule under the guise of an SMFP adjustment. Cardiac cath volumes are down across the State, and Johnston Health's own volumes are very low. The latest reported volume for all catheterization procedures is 63,871, down from a high of 84,662 in 2005. Similarly, 2011 PCI volumes were at 28,389, down from a high of 30,771 in 2004. Johnston Memorial Hospital's own catheterization volumes have been steadily declining, from 1057 in 2005 to 292 in 2011.

In short, there is sufficient cardiac cath capacity that is readily accessible and available in the State, which should be the focus of the SHCC. Johnston Health's request is devoid of any argument based upon need for additional access or capacity at its own facility or within the geographic area it serves.

5. Grandfathering Is a Well-Established and Necessary Practice in Amending Existing Laws

Johnston Health complains that grandfathered cardiac cath providers have an unfair advantage because they can perform therapeutic procedures without the availability of open heart surgery in the same facility, while providers subject to the Cardiac Cath Support Rule cannot. However, the use of a grandfathering mechanism to protect the vested rights of persons and entities under prior law, is a basic and inherent tenet of changing statutes and regulations which is a legally necessary aspect of such amendments to the law. This well-established practice is designed to ensure fairness and equity for those with vested rights under pre-existing law, and does not in any way justify the unusual action sought in Johnston Health's Petition. Taken to its logical conclusion, Johnston Health's cry of inequity would essentially mean that no new legal or regulatory restrictions could ever be imposed upon health care providers.

Conclusion

For all of the reasons set forth above, DLPCP respectfully urges the SHCC to find that Johnston Health's Petition to allow any proposed change to cardiac catheterization regulations should be reviewed and evaluated pursuant to the permanent rulemaking procedure created by statute for such changes; and that the issues raised in the Petition are not appropriate for consideration as part of the summer cycle of special need adjustments for the 2013 SMFP. Thank you for your attention to these important issues.

- DEPARTMENT OF HEALTH HOME
- DEPARTMENT OF HEALTH INFORMATION
- HEALTH TOPICS A-Z
- BIRTH AND DEATH CERTIFICATES
- HEALTHY LIVING
- HEALTHY SCHOOLS, BUSINESSES AND COMMUNITIES
- HEALTH STATISTICS AND RESEARCH
- HEALTH SERVICES AND RESOURCES
- PUBLIC HEALTH PREPAREDNESS
- FACILITIES, PROVIDERS & MANAGED CARE PLANS
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  - Drugs, Devices & Cosmetics
  - Health Facility Licensure Regulations
  - Healthcare Associated Infections
  - Hearing Aids
  - Home Health Services and Hospices
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  - Chapter 51 questions and answers
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  - Access to Advanced Cardiac Care
  - Sexual Assault Resources
  - Intermediate Care Facilities
  - Laboratories
  - Managed Care
  - Nurse Aide Registry
  - Nursing Home Care
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- DISEASES AND CONDITIONS
- NEWSROOM, PUBLICATIONS AND REPORTS

LOG IN

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Access to Advanced Cardiac Care

Percutaneous coronary intervention (PCI), also known as coronary angioplasty, is among the most advanced treatments available to open blocked arteries in the heart, thereby preventing or treating a heart attack. The procedure may be done on an elective, scheduled basis when the patient is free of symptoms or it may be done on an emergent (primary) basis when the patient is having a heart attack. In either the elective or primary setting, it involves inserting a thin, pliable catheter into a major blood vessel of the arm or leg and manipulating the tip of the catheter to the heart. Then a balloon or mechanical stent at the tip of the catheter is used to reopen blocked or partially blocked arteries and restore blood flow to the heart muscle. When the procedure is done in appropriate patients, the benefit can be great. If President Bill Clinton had been a suitable candidate with less extensive disease, he might have gone home later the same day of the procedure with a small puncture wound in the arm or leg, his heart problem fixed, and resumption of his usual life in a few days.

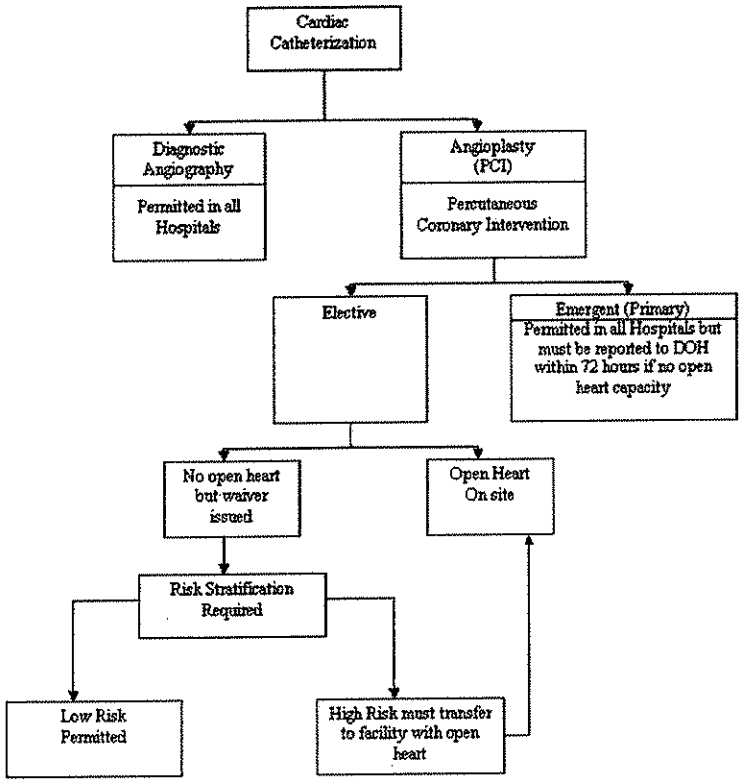
Department regulations state that PCI may be performed only in a hospital that has an open heart surgery program onsite. These regulations are consistent with the current guidelines of the American College of Cardiology (ACC). This is a safety measure to deal with possible complications that may be severe enough to require emergency open heart surgery. Over recent years, however, PCI has evolved and improved so that such complications do not occur as frequently as they once did. In any event, Department regulations allow PCI to be done in any hospital without a formal PCI program and open heart surgery program onsite if it is an emergency situation.

Hospitals in rural and medically underserved areas have petitioned the Department to waive the regulations requiring onsite open heart surgery as a prerequisite to offering PCI to their patients. Their premise is that access to the benefits of PCI should not be denied to patients as a consequence of geography or demographics. To explore the notion of improving access to care, a decision was made to allow PCI in a few community hospitals without onsite cardiac surgery as part of a limited program involving a waiver of Department regulations. Participating hospitals must agree to certain operating conditions that are largely based on the 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.

Hospitals in the PCI project must report their performance data to the Department. This is done through an intermediary entity, the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). The Department chose to utilize the NCDR because it is a mature system that has been collecting and analyzing PCI data for over five years and currently does so for more than 350 hospitals. Member hospitals are required to fill out a standardized record for every patient who undergoes PCI and submit that raw data to the NCDR. As data is analyzed, a member hospital receives a confidential institutional report on a quarterly and annual basis that addresses various outcomes including success, adverse events and mortality. The report compares a hospital's performance to an NCDR benchmark, to a national average of all member hospitals, and to a comparison group consisting of hospitals that perform a comparable volume of cardiac catheterization procedures. This comparative data is more robust than if the Department had just collected data from participating facilities. Hospitals in the PCI project must share their institutional reports with the Department.

The Department is using the NCDR reports to monitor outcomes to help prevent or minimize harm to patients while permitting the benefits of PCI to become available in medically underserved geographic areas. As experience and data accumulate, decisions will be made regarding a hospital's continued participation in the project. Furthermore, action may be warranted regarding the regulations that govern PCI. Possible options span the gamut from dropping the regulations, or keeping the regulations and allowing waivers, to keeping the regulations with no waivers. At this time, however, the Department does not intend to grant any additional waiver requests to participate in the PCI project.

CARDIAC CATHETERIZATION DIAGRAM



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PENNSYLVANIA ADMINISTRATIVE CODE
Commonwealth of Pennsylvania
Pennsylvania Codes

*** This document is current through the August 2012 supplement ***
*** Changes effective through 42 Pa.B. 3422 (June 9, 2012). ***

TITLE 28. HEALTH AND SAFETY
PART IV. HEALTH FACILITIES
SUBPART B. GENERAL AND SPECIAL HOSPITALS
CHAPTER 138. CARDIAC CATHETERIZATION SERVICES
GENERAL PROVISIONS

28 Pa. Code § 138.2 (2012)

§ 138.2. Definitions

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Board certified -- A physician licensed to practice medicine in this Commonwealth who has successfully passed an examination and has maintained certification in the relevant medical specialty or subspecialty area, or both, recognized by one of the following groups:

(i) The American Board of Medical Specialties.

(ii) The American Osteopathic Association.

(iii) The foreign equivalent of either group listed in subparagraph (i) or (ii).

Cardiac catheterization -- A procedure used to diagnose and treat various cardiac and circulatory diseases that involves inserting a thin, pliable catheter, which is viewable by X-ray, into a major blood vessel of the arm or leg, and manipulating the tip of the catheter through veins or arteries to the heart.

Cardiac catheterization area -- That portion of the hospital dedicated to the performance of cardiac catheterizations, including the cardiac catheterization laboratory where the invasive procedures are performed by the physician, and preoperative and postoperative recovery units used for treatment of the cardiac catheterization patient.

Electrophysiology study (EPS) -- diagnostic -- The use of blood vessel access to position electrode catheters in various intra cardiac locations with the help of fluoroscopy for the purpose of recording the timing of electrical events to assess the location and direction of impulse propagation. The term includes procedures designed to induce ventricular

or supraventricular tachycardia and activation sequence mapping of cardiac tachyarrhythmias.

Electrophysiology study (EPS) -- therapeutic -- EPS used as or in combination with a therapeutic procedure, which includes electrode catheter ablative procedures and implantation of antitachyarrhythmia devices and implantable cardiovertor defibrillators.

High-risk cardiac catheterization -- Cardiac catheterization which presents a high risk of significant cardiac complication. The term includes diagnostic cardiac catheterization procedures that present a high risk of significant cardiac complication, PTCA, pediatric cardiac catheterization and therapeutic electrophysiology except for the implantation of routine permanent pacemakers.

Low-risk cardiac catheterization -- Cardiac catheterization which is not high-risk cardiac catheterization.

Onsite -- In the physical structure at which cardiac catheterization services are being offered or in an adjoining structure.

PTCA -- Percutaneous transluminal coronary angioplasty -- A procedure which uses a balloon catheter, plaque removing device, laser device or mechanical stent to re-open collapsed, blocked or partially blocked arteries.

Pediatric cardiac catheterization -- The performance of cardiac catheterization on a person who is under 18 years of age except for those patients whose physical development, in the judgment of the patient's physician, allows the patient to receive treatment safely and appropriately in hospitals that do not have pediatric cardiac catheterization programs.

Preboard certification status -- A physician licensed to practice medicine in this Commonwealth who has completed the requirements necessary to take a certification examination offered by a medical specialty board recognized by the American Board of Medical Specialties, the American Osteopathic Association, or the foreign equivalent of either group, and who has been eligible to take the examination for no longer than 3 years.

Twenty-four hours per day -- Refers to the availability or onsite presence of specific personnel, support services or equipment on a 24-hour-per-day, 7-days-a-week basis.

PROGRAM, SERVICE, PERSONNEL AND AGREEMENT REQUIREMENTS

HIERARCHY NOTES:

Title Note
Part Note
Subpart Note
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PENNSYLVANIA ADMINISTRATIVE CODE
Commonwealth of Pennsylvania
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GENERAL PROVISIONS

28 Pa. Code § 138.15 (2012)

§ 138.15. High-risk cardiac catheterizations

A hospital may perform high-risk cardiac catheterizations only if it has an open heart surgical program onsite.

HIERARCHY NOTES:

Title Note
Part Note
Subpart Note
Chapter Note

PENNSYLVANIA ADMINISTRATIVE CODE
Commonwealth of Pennsylvania
Pennsylvania Codes

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TITLE 28. HEALTH AND SAFETY
PART IV. HEALTH FACILITIES
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CHAPTER 138. CARDIAC CATHETERIZATION SERVICES
GENERAL PROVISIONS

28 Pa. Code § 138.16 (2012)

§ 138.16. Transfer agreements for low-risk cardiac catheterization hospitals

(a) A hospital that does not have an open heart surgical program onsite may perform low-risk cardiac catheterizations if the hospital has protocols for distinguishing between low and high-risk cardiac catheterization patients and a formal written agreement with at least one hospital that does have an open heart surgical program onsite, which agreement includes the following:

(1) Protocols addressing indications, contraindications and other criteria for the emergency transfer of patients in a timely manner.

(2) Assurance of transfer of patients to an open heart surgery program and initiation of open heart surgery in a timely manner.

(3) Provision for semiannual data exchange on performance between the hospitals party to the agreement.

(4) Specification of mechanisms for continued substantive communication between the hospitals party to the agreement, and between their sending and receiving physicians.

(b) The agreement shall remain continuously in effect and be reviewed at least annually.

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GENERAL PROVISIONS

28 Pa. Code § 138.17 (2012)

§ 138.17. PTCA

(a) In a hospital in which elective PTCA is performed, each physician performing PTCAs shall be either Board certified or shall have attained preboard certification status in cardiovascular diseases with specialized and appropriate training in interventional cardiology procedures.

(b) A rigorous mechanism for valid peer review shall be established and ongoing in a hospital offering PTCA services.

(c) If a hospital that does not have an open heart surgery program onsite performs an emergent PTCA, the hospital shall report the circumstances to the Department in writing within 72 hours.

HIERARCHY NOTES:

Title Note
Part Note
Subpart Note
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CODE OF MARYLAND REGULATIONS

This document is current through the 7/27/12 issue of the Maryland Register

TITLE 10. DEPARTMENT OF HEALTH AND MENTAL HYGIENE
SUBTITLE 24. MARYLAND HEALTH CARE COMMISSION
CHAPTER 05. CONTINUATION OF NON-PRIMARY RESEARCH WAIVERS THROUGH PARTICIPATION IN THE FOLLOW-ON C-PORT E REGISTRY

COMAR 10.24.05.01 (2012)

.01 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Commission" means the Maryland Health Care Commission.

(2) "C-PORT study" means a randomized clinical research trial conducted by the Atlantic Cardiovascular Patient Outcomes Team (C-PORT) to determine whether nonprimary PCI performed in hospitals without on-site cardiac surgery services is as safe and effective as nonprimary PCI performed in hospitals with on-site cardiac surgery services.

(3) "Nonprimary percutaneous coronary intervention" means PCI capable of relieving coronary vessel narrowing associated with coronary artery disease unrelated to ST-segment elevation myocardial infarction and includes elective PCI.

(4) "Percutaneous coronary intervention (PCI)" means a variety of catheter-based techniques, including balloon angioplasty, capable of relieving coronary vessel narrowing.

(5) "Primary PCI" means PCI capable of relieving coronary vessel narrowing associated with ST-segment elevation myocardial infarction (STEMI).

(6) "Regional service area" means the area used for planning for cardiac surgery and PCI services, as provided in the State Health Plan, *COMAR 10.24.17.*

(7) Registry means the C-PORT E Registry of Non-Primary PCI that follows-on the C-PORT E Study of Non-Primary PCI and that is:

(a) Maintained by the Principal Investigator in the C-PORT E Study of Non-Primary PCI;

(b) Overseen by the Johns Hopkins Institutional Review Board;

(c) Overseen by a Data and Safety Monitoring Board.

(8) "STEMI" means coronary vessel narrowing associated with ST-segment elevation myocardial infarction.

(9) "Waiver to perform nonprimary PCI" means a time-limited exemption from the requirements of COMAR 10.24.17.04E, Policy 5.0, by which the Commission permits an acute care hospital without on-site cardiac surgery services to perform nonprimary PCI services within the C-PORT study.

(10) "Waiver to perform primary PCI" means a time-limited exemption from the requirements of COMAR 10.24.17.04E, Policy 5.0, by which the Commission permits an acute care hospital without on-site cardiac surgery services to perform primary PCI services.

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CODE OF MARYLAND REGULATIONS

This document is current through the 7/27/12 issue of the Maryland Register

TITLE 10. DEPARTMENT OF HEALTH AND MENTAL HYGIENE
SUBTITLE 24. MARYLAND HEALTH CARE COMMISSION
CHAPTER 05. CONTINUATION OF NON-PRIMARY RESEARCH WAIVERS THROUGH PARTICIPATION IN THE FOLLOW-ON C-PORT E REGISTRY

COMAR 10.24.05.02 (2012)

.02 Purpose.

A. In 2007, the Commission established a one-time process by which certain licensed acute general hospitals without on-site cardiac surgery services were awarded time-limited research waivers from the requirements of COMAR 10.24.17.04E, Policy 5.0, and were permitted to provide non-primary PCI services as part of the C-PORT E study to assess the safety and efficacy of providing non-primary PCI services for certain patient groups without on-site cardiac surgery, as provided in COMAR 10.24.17.04E, Policy 5.3.

B. In 2007, the Commission determined that the C-PORT E study offered a means of acquiring information to support future evidence-based State health care policy and planning with regard to cardiovascular services.

C. As the C-PORT E research study nears the attainment of its patient accrual target, the principal investigator of the research study has recommended that the Commission continue the C-PORT E research waiver of each hospital that is in good standing so that each such hospital will not have to shut down its program while the required follow-up data on C-PORT E patients is collected and analyzed.

D. The Commission has determined that the term of an existing research waiver held by a hospital that maintains good standing under the Commissions requirements should be extended while the hospital participates in the Registry, thereby permitting the hospital to continue to perform non-primary PCI under the limitations and for the Registry term provided in these regulations until such time as the Commission has the information from the research study that is needed to guide State policy about the regulation of non-primary PCI.

E. The Commission shall consider data collected by the C-PORT E study and information from the Registry in updating its State Health Plan for cardiovascular services, including planning policies governing the requirement to have cardiac surgical services on-site for non-primary PCI. The analysis conducted as part of this update will consider the system impact, including access, cost-effectiveness, and quality implications, of non-primary PCI being performed in hospitals without on-site cardiac surgery.

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COMAR 10.24.05.04 (2012)

.04 Review of Applications for Participation in Registry.

A. Review Criteria.

(1) An applicant C-PORT E research waiver hospital shall meet the study site inclusion criteria established in the Atlantic C-PORT E research study protocol.

(2) An applicant shall document that it will meet the criteria established in the manual of operations of the C-PORT E Registry of Non-Primary PCI that follows-on the C-PORT E Study of Non-Primary PCI.

(3) An applicant shall document that it will continue to satisfy the following requirements:

(a) For institutional resources:

(i) An applicant shall maintain a patient prioritization plan that guarantees that a patient who requires primary PCI for STEMI is given immediate preference for care in the cardiac catheterization laboratory;

(ii) An applicant shall maintain a formal and properly executed written agreement with a tertiary care center that provides for the unconditional transfer of each non-primary PCI patient who requires additional care, including emergent or non-primary cardiac surgery or PCI, from the applicant hospital to the tertiary institution; and

(iii) An applicant shall maintain its agreement with an advanced cardiac support emergency medical services provider that guarantees arrival of the air or ground ambulance at the applicant hospital within 30 minutes of a request for non-primary PCI patient transport by the applicant;

(b) For physician resources, an applicant shall maintain adequate staff necessary for the provision of primary and non-primary PCI services, including a minimum of three interventional cardiologists who:

(i) Meet the requirements in the C-PORT E study research protocol and in *COMAR 10.24.17*, Table A-1;

(ii) Can be available on-site within 30 minutes when on call; and

(iii) Agree to abide by the Device Selection Criteria in the applicable Manual of Operations;

(c) For minimum volumes, an applicant shall maintain a minimum volume of 200 PCI procedures during each year of its waiver;

(d) For follow-up of patients enrolled in the C-PORT E study, an applicant shall maintain a patient follow-up rate of 98 percent; and

(e) For follow-up of patients enrolled in the Registry, an applicant shall commit to patient follow-up through hospital discharge.

(4) In determining whether to extend the research waiver of an existing C-PORT E research waiver hospital and permit it to enter the Registry, the Commission shall consider appropriate factors, including:

(a) An applicants current performance under its non-primary PCI research waiver; and

(b) An applicants current performance under its primary PCI waiver.

B. The Commission staff shall prepare a staff recommendation on an application to enter the Registry for consideration by the Commission.

C. The burden of proof that a non-primary research waiver hospital meets the applicable review criteria rests with the applicant.

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COMAR 10.24.05.06 (2012)

.06 Conditions for Maintaining a Waiver.

A. A hospital with a waiver to perform non-primary PCI shall notify the Commission in writing within 3 business days of the occurrence of any of the following:

(1) The hospital performs non-primary PCI on a patient not enrolled in the C-PORT E study or in the Registry;

(2) The hospital's primary PCI waiver expires, is relinquished, or is withdrawn;

(3) The hospital fails to notify the Commission of death or coronary artery bypass surgery experienced by a patient participating in the C-PORT E study or in the Registry;

(4) The hospital fails to perform a minimum of 200 PCI procedures during the second and each subsequent year after it received a non-primary PCI research waiver from the Commission; or

(5) The hospital fails to meet and maintain the criteria required by the Commission for participation in the C-PORT E study, or its participation in the C-PORT E study or in the Registry ends for any reason.

B. A hospital required to give notice under § A of this regulation, shall, on written notice from the Commission, immediately relinquish its waiver to perform nonprimary PCI.

C. A hospital with a waiver to perform nonprimary PCI shall notify the Commission in writing if there are any changes to the facts or representations made in its waiver application or in any supplemental documents provided to the Commission.

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COMAR 10.24.05.07 (2012)

.07 Waiver Performance and Monitoring.

A. Each hospital granted a waiver to perform non-primary PCI within the C-PORT E study or within the Registry shall provide data to the Commission in a form and manner acceptable to the Commission.

B. Each hospital granted a waiver to perform non-primary PCI within the C-PORT E study or within the Registry shall submit periodic progress reports in a format specified by the Commission and, at the conclusion of the research project and, if requested, at the end of the Registry, submit final reports in a form and manner acceptable to the Commission, as provided in COMAR 10.24.17.05D(2)(d).

C. Each hospital granted a waiver to perform non-primary PCI within the C-PORT E study or within the Registry shall authorize the C-PORT E study principal investigator and the Registry coordinator to provide data requested by the Commission.

MARYLAND
HEALTH CARE
COMMISSION

Required Under House Bill 800 (2007)
Maryland Health Care Commission – Program Evaluation

Certificate of Need – Update on Implementation of Recommendations:

- 2005 Certificate of Need Task Force
- Comprehensive Evaluation Required by Chapter 702 of 1999

October 1, 2008

Marilyn Moon, Ph.D.
Chair

Rex W. Cowdry, M.D.
Executive Director

Implementation Update: Recommendations from the 2001-2002 Analysis and Evaluation of Certificate of Need Regulation in Maryland (Phase I and Phase II Final Reports to the Maryland General Assembly)

Report and Service	Recommendation	Implementation Progress
Phase I: Final Report to the Maryland General Assembly • Obstetric Services	**Recommendation 1.0** The Commission should continue its regulatory oversight of acute inpatient obstetric services through the Certificate of Need program. **Recommendation 1.1** The Commission should modify the need projection, review threshold, and approval policies found in the State Health Plan to permit its consideration of proposed new obstetric services.	The establishment of a new acute inpatient obstetric service continues to be regulated under the CON program in Maryland. The Commission adopted a new chapter of the State Health Plan (COMAR 10.24.12) effective April 15, 2005 for Acute Hospital Inpatient Obstetric Services. The new plan modified the policies governing consideration of a new obstetric service consistent with Recommendation 1.1.
• Cardiac Surgery and Therapeutic Catheterization Services	**Recommendation 2.0** The Commission should continue its regulatory oversight of open heart surgery services through the Certificate of Need program. **Recommendation 2.1** The Commission should establish an Advisory Committee on Outcome Assessment in Cardiovascular Care. **Recommendation 2.2** The Commission should use a well-designed research project to investigate cardiac surgical support for specific groups of patients receiving elective angioplasty.	The establishment of new OHS services continues to be regulated under the CON program in Maryland. The Commission established an Advisory Committee on Outcome Assessment in Cardiovascular Care in 2002. The Advisory Committee and its subcommittees completed their work in 2005. The cardiac services Chapter of the State Health Plan effective March 15, 2004 permits research waiver applications for a study of the safety and efficacy of non-primary PCI in hospitals without on-site cardiac surgery. A research proposal was

Report and Service	Recommendation	Implementation Progress
		submitted for review in 2005 and subsequently withdrawn prior to Commission action. A revised research proposal was submitted in 2006. After review by a Research Proposal Review Committee, the revised proposal was accepted by the Commission in April 2007. On October 22,, 2007, regulations became effective that guide the submission of research waiver applications to participate in a research project conducted by the Atlantic C-PORT project. The Commission awarded 4 non-primary percutaneous coronary intervention research waivers in the metropolitan Regional Service Areas in September 2008, and took no action on 3 applications pending receipt and review of waiver applications from the Western Maryland Regional Service Area.
	Recommendation 2.3 The Commission will continue to coordinate its planning and regulatory activities with other entities for the purpose of promoting affordable, accessible, high quality care for all residents of the state. The Maryland Health Care Commission and Health Services Cost Review Commission should monitor changes in market demand and referral patterns as a result of new or expanded open heart surgery services that may affect Maryland's Medicare waiver.	The Commission coordinates its planning and regulatory activities on an on-going basis.
	Recommendation 2.4 The Commission should have the authority to revoke its certification if an operating service fails to meet the standards adopted by the Commission. The Commission should conduct a study before seeking the required statutory change.	As a condition of issuing a CON to establish a new OHS program, the Commission requires the program to achieve minimum volume standards within 24 months of beginning operation and maintain the minimum utilization level in each subsequent year of operation. This condition has been applied in the approval of two OHS programs: Sacred Heart Hospital and Suburban Hospital. The Commission has not obtained authority to revoke the certification of an existing OHS program that was approved prior to 1997. In terms of the minimum volume requirement, Prince George's