

1 **EXCEPTION COMMITTEE PROCEDURE:**

2 **ELECTIVE PERCUTANEOUS CORONARY INTERVENTIONS (PCI)**

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4 The Department of Health's (Department) highest priority is to protect the health, safety and
5 welfare of the commonwealth's citizens. This commitment includes the commonwealth
6 citizens' need for reasonable access to cardiac diagnostic and treatment services. Within the
7 mandate to ensure the delivery of safe, quality health care services, the Department is sensitive
8 to the need to support development of new, evolving programs of care, while minimizing risk
9 associated with new technology and newly trained operators and support staff.

10 This paper addresses the Department's policy on PCI and rationale for decisions supporting the
11 policy position.

12 **GENERAL OVERVIEW OF PCI**

13 Percutaneous coronary interventions (PCI) refers to an invasive procedure that provides
14 treatment for patients with coronary artery disease. Because PCI is less invasive and less
15 traumatic than coronary artery bypass surgery, in many situations, this procedure is the
16 treatment of choice to relieve symptoms related to coronary artery disease (narrowing and
17 blockages).

18 In years past, when the overall PCI complication rate was 10 percent, the standard of care was to
19 limit PCI services to only those hospitals that also had onsite cardiac surgery services.

20 Numerous studies now demonstrate that, with improved technology and techniques, the PCI
21 complication rate has decreased dramatically, and mortality has fallen for all PCI procedures,
22 allowing for PCI procedures to be performed with acceptable outcomes in facilities without
23 onsite cardiac surgery capacity. Currently, approximately 17 Pennsylvania hospitals that do not
24 have cardiac surgery services perform elective high risk cardiac catheterization, which includes
25 PCI.

26 In Pennsylvania, the Department of Health permits all hospitals with the capacity to perform
27 PCI to do so on an emergency basis, allowing, for example, treatment for acute myocardial
28 infarction, because the lifesaving nature of the procedure outweighs the known risk. (28 PA
29 Code §138.17(c)) However, performing elective PCI without onsite cardiac surgery services is
30 currently permitted only by exception in Pennsylvania hospitals that do not also offer cardiac
31 surgery onsite.

32 Pa. Department of Health hospital regulations in 28 PA Code Chapter 138 address cardiac
33 catheterization services. §138.15 states "A hospital may perform high-risk cardiac

34 catheterization only if it has an open heart surgical program onsite.” High risk cardiac
35 catheterization is defined to include¹:

36 diagnostic cardiac catheterization procedures that present a high risk of significant
37 cardiac complication;

38 percutaneous transluminal coronary angioplasty (PTCA);

39 pediatric cardiac catheterization; and

40 therapeutic electrophysiology except for the implantation of routine permanent
41 pacemakers.

42 The Department’s regulations (28 PA Code §138.16) permit low-risk/diagnostic cardiac
43 catheterizations² to be performed in a hospital that does not have an open heart surgical
44 program onsite if the hospital has protocols for distinguishing between low- and high-risk
45 cardiac catheterization patients and has a formal written agreement with at least one hospital
46 that does have an onsite open heart surgical program.

47 The regulatory requirement that all hospitals providing cardiac catheterization
48 services report to the Department (28 PA Code §138.20(b)) is now integrated in reports made to
49 the Pennsylvania Healthcare Cost Containment Council (PHC4).

50 The Department’s regulations also authorize exceptions to the regulations in certain
51 circumstances defined by the Department.³ Exceptions are considered if a facility meets the
52 Department’s pre-defined requirements and demonstrates that adherence to a regulation
53 constitutes an unreasonable hardship. Hospitals granted an exception must submit specified
54 documents to the Department and demonstrate, through evidence at the time of licensure
55 survey, that they are meeting the terms under which the exception was originally granted.

56 Beginning in 2001, the Department granted four hospitals without onsite cardiac surgery
57 capacity an exception to allow them to perform elective PCI. These hospitals were
58 required to meet specified conditions related to physician operators, quality oversight, and
59 reporting. In 2005, the Department added the requirement that hospitals requesting this
60 exception also participate in a research study conducted by The Johns Hopkins University. In
61 order to participate in the study, hospitals had to perform a minimum of 200 angioplasty

¹ See definition at 28 PA Code §138.2.

² Defined in 28 PA Code §138.2

³ See, 28 PA Code §51.31- 51.34 regarding the exceptions.

62 procedures each year and develop a formal angioplasty development program to prepare their
63 staff and establish protocols and policies. Pennsylvania facilities without onsite cardiac surgery
64 are permitted by exception to offer elective PCI.

65 All hospitals without cardiac surgery programs that have been approved
66 to perform PCI are now required to participate in the National Cardiovascular Data Registry
67 (NCDR) CathPCI Registry, which collects detailed clinical, process-of-care and outcomes data for
68 patients undergoing coronary angiography and PCI in the United States. The registry
69 contributes to improvements in quality of care by providing feedback data on a wide range of
70 performance metrics to participating facilities. The facilities can evaluate how their
71 performance compares with like-sized hospitals and the national aggregate. This aids programs
72 in the development of quality improvement initiatives and helps facilities to define
73 performance goals.

74 The department is using the NCDR reports to monitor outcomes in order to help prevent or
75 minimize harm to patients, while still permitting the benefits of PCI to be available in medically
76 underserved geographic areas.

77 **DEFINITIONS**

78 Notwithstanding regulatory definitions hereinabove discussed, in this paper, words and terms
79 have the following meanings, unless the context clearly indicates otherwise:

80 “Cardiac catheterization” refers to the invasive, non-surgical diagnostic procedure used to
81 study the coronary arteries and heart.

82 “PCI” refers to therapeutic interventions for treatment of coronary artery disease, such as stent
83 placement or angioplasty (including percutaneous transluminal coronary angioplasty [PTCA]).
84 Therapeutic catheterization is included in the definition of PCI.

85 “Elective PCI” refers to PCI procedures that are not performed in emergency circumstances.

86 “Primary PCI” means PCI performed in emergency circumstances.

87 **SCIENTIFIC AND CLINICAL EVIDENCE**

88 When coronary artery disease (CAD) is diagnosed, choice of treatment must be based on risk
89 factors such as the patient’s overall health and cardiovascular health history, nature and extent
90 of CAD, presence of other active chronic disease such as diabetes, and the urgent or emergent
91 need for treatment based on the patient’s presenting symptoms. PCI is often the treatment of

92 choice over the more invasive coronary arterial bypass graft (CABG) surgery for treatment of
93 coronary artery disease. The need for emergency CABG has dramatically decreased with
94 advances in PCI technology, particularly coronary stents.

95 In order to safely offer elective PCI in hospitals without the ability to perform CABG onsite, very
96 careful screening and selection of patients is critical. Equally important, however, are the
97 expertise of the physician operator and the experience of the facility in which the procedure is
98 performed. It is generally accepted that a direct relationship exists between procedural volume
99 and outcomes. Therefore, one quality parameter that has been suggested for elective PCI is the
100 number of procedures per year. Consequently, much of the medical literature has looked at
101 volume as a measure of quality. While volume may be an important indicator of quality, other
102 indicators may be as important as or even more important than volume for measurement of
103 safety and quality. Thus, the latest ACCF/AHA/SCAI 2013 Clinical Competence
104 Statement⁴ cautions against overemphasis on specific volume recommendations, recognizing
105 that volume is just one of many factors related to clinical outcomes. Other groups have added
106 other quality measures to volume measures, while other international groups have avoided
107 giving specific volume recommendations for operator or facilities altogether.

108 Additionally, according to the Agency for Healthcare Research and Quality (AHRQ), the volume-
109 outcome relationship may not hold over time as providers become more experienced or as
110 technology changes. It is unclear whether simply increasing volume at low volume hospitals
111 would actually improve outcomes. It is possible that hospitals could increase volume simply by
112 increasing the number of borderline or inappropriate procedures performed. In the concluding
113 statement on the relationship of volume to operator and clinical competency in the May 2013
114 consensus document, the study authors confirm that there was no relationship between higher
115 volumes and improved outcomes above a PCI volume of 200⁵. While the ACCF/AHA/SCAI
116 recommends a minimum institutional volume of 200 PCIs per year, they recommend that those
117 facilities that have less than 200 cases annually must have stringent systems and process
118 protocols, close monitoring of clinical outcomes and additional strategies that promote
119 adequate operator and staff experience. They must also be in locations where access to
120 PCI service is limited. This posits that poor case outcomes associated with PCI volume
121 below 200 can be mitigated by rigorous adherence to quality standards.

⁴ Also known as “2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures”, by ACCF/AHA/SCAI (A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physician Task Force on Clinical Competence and Training)

⁵ Also known as “2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures”, by ACCF/AHA/SCAI (A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physician Task Force on Clinical Competence and Training)

122 An external review process provides one way to determine if the quality standards that are
123 recommended are being instituted with the necessary rigor in order to protect patient safety.
124 External accreditation and external quality review are generally accepted strategies for
125 hospitals to use for program quality assurance. Accreditation generally includes retrospective
126 review of angiography films, hospital policies and procedures, and patient outcomes. External
127 quality review will permit experts in the field to conduct an unbiased evaluation of all PCI
128 services to accepted quality standards.

129 **POLICY DISCUSSION**

130 In developing its policy position, the Department conducted an extensive review of national
131 research findings and outcome study data, PHC4 PCI data, and outcome data the Department
132 collected in August 2012. The Department also reviewed current national PCI guidelines and
133 practice standards. In addition, the Department reviewed the regulatory approaches to PCI
134 taken by other state governments.

135 The Department has also considered the merits of external audit as a quality improvement tool
136 and external national certification as a quality assurance measure.

137 Data from several voluntary databases confirm that doing PCI in hospitals without onsite
138 cardiac surgery is a national trend that is increasing. The NCDR indicate that on-site cardiac
139 surgery was not available in 83 percent of facilities performing fewer than 200 PCIs annually.⁶
140 A 2009 study analyzing the NCDR CathPCI Registry data confirmed the safety of PCI without
141 onsite cardiac surgery available, provided that rigorous clinical, operator, and institutional
142 criteria are in place and are monitored to assure high quality outcomes.⁷ Another study, called
143 the Cardiovascular Patient Outcomes Research Team Elective Angioplasty Study (C-PORT-E),
144 concluded that patients who have non-emergency angioplasty to open blocked heart vessels
145 have no significantly greater risk of death or complications when they have the procedure at
146 hospitals without cardiac surgery backup.⁸

⁶ J Am Coll Cardiol. 2012 Nov 13;60(20):2017-31 and Epub 2012 Oct 17. "A Contemporary View of Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention in the United States: A Report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011" Dehmer GJ, Weaver D, Roe MT, Milford-Beland S, Fitzgerald S, Hermann A, Messenger J, Moussa I, Garratt K, Rumsfeld J, Brindis RG.

⁷ J Am Coll Cardiol. 2009 Jun 30;54(1):16-24. "News from the NCDR: Percutaneous Coronary Interventions in Facilities without Cardiac Surgery Onsite: A report from the National Cardiovascular Data Registry (NCDR)" Kutcher MA, Klein LW, Ou FS, Wharton TP, Dehmer GJ, Singh M, Anderson VA, Rumsfeld JS, Weintraub WS, Shaw RE, Sacrinty MT, Woodward A, Peterson ED, Brindis RG.

⁸ N Engl J Med. 2012 May 10; 366(19):1792-1802. "Outcomes of PCI at Hospitals with or without On-Site Cardiac Surgery" Aversano T, Lemmon CC, Li L.

147 The C-PORT-E was a multistate trial that studied patients treated with PCI in hospitals with low
148 volume and without cardiac surgery, comparing them to those patients treated at hospitals
149 with onsite cardiac surgery. This study included many of the hospitals that perform PCI without
150 onsite cardiac surgery in Pennsylvania and followed the development of these programs from
151 the beginning of the PCI programs.⁹ The median number of procedures for all patients in this
152 study was 150 procedures. It was found that patients treated in hospitals without onsite
153 cardiac surgery had no greater risk of mortality and comparable risks of major adverse cardiac
154 and cerebral complications when compared to those who were treated at hospitals with onsite
155 cardiac surgery. This study showed that, under certain conditions, it was possible for a low
156 volume hospital to perform PCI with results similar to those in hospitals with onsite surgery.

157 Multiple studies have identified patient variables that affect PCI outcomes, regardless of
158 whether or not it is performed where cardiac surgery is available onsite. Changes in
159 technology and clinical practice as well as care needs of the population will continue to affect
160 the state of the art and standards of practice for PCI.

161 In developing the requirements for this exception, the department has taken into consideration
162 the ACCF/AHA/SCAI 2011 guidelines as updated in 2013.¹⁰

- 163 • “Primary PCI is reasonable in hospitals without on-site cardiac surgery, provided that
164 appropriate planning for program development has been accomplished.
- 165 • Elective PCI might be considered in hospitals without onsite cardiac surgery, provided
166 that appropriate planning for program development has been accomplished and
167 rigorous clinical and angiographic criteria are used for proper patient selection.
- 168 • Primary or elective PCI should not be performed in hospitals without on-site cardiac
169 surgery capabilities without a proven plan for rapid transport to a cardiac surgery
170 operating room in a nearby hospital or without hemodynamic support capability for
171 transfer.”

172 ACCF/AHA/SCAI guidelines also make recommendations about PCI volume and experience for
173 physician operators and facilities. The Department’s authority for regulating health care
174 facilities does not include regulation of individual practitioners practicing in those facilities.
175 However, the Department does set standards that hold facilities accountable for establishing
176 criteria for granting medical staff privileges and for internal quality assurance monitoring.

⁹ Agreements between the Department of Health and the Pennsylvania hospitals performing elective PCI services without cardiac surgery units contained a provision that stated: “When the final report of the C-PORT E trial is issued, the Department will review the report and determine if future guidance for the provision of elective PCI procedures is necessary.” This policy statement provides that guidance.

¹⁰ ACCF/AHA/SCAI 2013 Clinical Competence Statement, pp. 16

177 The ACCF/AHA/SCAI guidelines advise careful consideration of elective/urgent PCI performed
178 by low-volume operators at low volume centers, regardless of onsite cardiac surgery.

179 As PCI continues to be an evolving area of practice, the Department has determined that the
180 best way to insure that departmental policy keeps up with the rapid changes in PCI practice is
181 to create mandatory oversight requirements in addition to certain documentary obligations as
182 part of any exception that may be granted. This will permit the Department to monitor facility
183 compliance with the requirements outlined in this document, as well as to continuously
184 review data from all hospitals performing PCI. The Department's focus will be on patient
185 outcomes as a measure of quality care rather than procedure volume as a proxy measure for
186 quality.

187 **EXCEPTION REQUIREMENTS**

188 **28 Pa. Code §138.15 High Risk Cardiac Catheterization**

189 **Recommendations**

190 The Department will permit hospitals that currently offer elective PCI without cardiac surgery
191 onsite to continue doing so provided that the Department's requirements below are met.

192 A hospital without cardiac surgery onsite that desires to establish a new elective PCI service
193 must apply for an exception. This hospital must meet the additional requirements below
194 before this new service is offered.

195 PCI services may not be limited to elective PCI. A full range of PCI services must be available.

196 **Minimum requirements for elective PCI (primary and elective) in hospitals without cardiac** 197 **surgery service onsite**

198 **1.All elective PCI Services**

- 199 a) Patient selection criteria and risk stratification, consistent with all current standards
200 identified as Class I recommendations by the ACCF, AHA, STS and AATS;¹¹
- 201 b) Standards for training and competency evaluation of physician operators and all
202 professional and technical staff;
- 203 c) Hospital requirements for credentialing of participating cardiologists/
204 operators/interventionalists, including PCI case volume (elective and primary);

¹¹ These recommendations and standards can be found in 2011 ACCF/AHA/SCAI Guidelines for PCI and associated update documents such as ACCF/SCAI/AATS/HFSA/SCCT 2012 "Appropriate Use Criteria for Coronary Revascularization Focused Update" and ACCF/AHA/SCAI 2013 "Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures". However, as these guidelines are regularly updated, standards will change to be consistent with the latest updated documents.

- 205 d) Twenty-four hour/7day availability of the PCI service, including qualified professional
206 and technical staff at the PCI hospital and cardiac surgery services available at a
207 transfer hospital;
- 208 e) Agreement with a nearby hospital with cardiac surgery service to provide consultation
209 and treatment as well as rapid transport of patients and the provision of hemodynamic
210 support capability;
- 211 f) Participation in the ACC-NCDR CathPCI Registry and authorization for the Department to
212 access the facility's registry data;
- 213 g) Quality assurance procedures that include policies for tracking and monitoring operator
214 and patient outcomes, including complication rates;
- 215 h) Review of risk-adjusted PCI outcomes of the facility, comparison to regional and national
216 benchmark data and incorporation of results for the improvement of quality of care; and
- 217 i) At least every five years, accreditation by Department-approved accreditation agency
218 with standards at least equal to those of the Accreditation for Cardiovascular Excellence.

219 **2. Low volume elective PCI Services (existing services, less than 200 annual procedures**
220 **combining primary and elective).**

- 221 a) As a modification to item 1(i) above: Annual accreditation by Department-approved
222 accreditation agency with standards at least equal to those of the Accreditation for
223 Cardiovascular Excellence

224 **3. New elective PCI Services**

225 In addition to the items in #1 above:

- 226 a) An agreement with a Department-approved accreditation agency and submission of an
227 exception request to begin the accreditation process, which, once approved, will be a
228 probationary exception to allow the accreditation process to begin;
- 229 b) Program development and implementation plan including timeline and business plan for
230 reaching and maintaining volume of at least 200 procedures annually;
- 231 c) Accreditation by Department-approved accreditation agency with standards at least
232 equal to those of the Accreditation for Cardiovascular Excellence prior to offering
233 services; and
- 234 d) Occupancy inspection by the Department, prior to offering services, pursuant to 28 PA
235 Code §51.3.

- 236 **Documentation to be provided to the Department by the facility as part of the exception**
237 **application:**
- 238 Policies and procedures outlining patient selection criteria and risk stratification, consistent
239 with all standards identified as Class I recommendations by the ACCF, AHA, STS and AATS;
- 240 Medical staff privileges and qualifications for performing PCI, including operator volume and
241 outcomes;
- 242 Standards for training and competency evaluation of physician operators and all professional
243 and technical staff;
- 244 Policies and procedures to assure 24hour/7day availability of PCI service, including qualified
245 professional and technical staff at the PCI hospital and cardiac surgery services at the transfer
246 hospital;
- 247 Periodic ACC-NCDR CathPCI Registry reports as requested by the Department and ongoing
248 departmental access to ACC-NCDR CathPCI Registry data.
- 249 Policies and procedures for regular internal review of the hospital's statistics and outcome
250 data;
- 251 Agreement with a nearby hospital with cardiac surgery service to provide consultation and
252 treatment, as well as rapid transport of patients and the provision of hemodynamic support
253 capability;
- 254 Transport policies and hemodynamic support procedures; and
- 255 Copy of most current approved accreditation report, no more than six months old.