

SYNOPSIS

Rule 111-2-2-.21

STATEMENT OF PURPOSE AND MAIN FEATURES OF PROPOSED RULE

The purpose of this proposed amendment is to modify an existing regulation to permit some hospitals to participate in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). This permission will be limited to no more than 3 years.

DIFFERENCES BETWEEN EXISTING AND PROPOSED RULES

The existing regulation is amended to add 111-2-2-.21(1)(d) to modify the applicability of the rule.

The existing regulation is amended to add 111-2-2-.21(3)(f)3 to permit certain hospitals accepted into the study with permission of the State to perform therapeutic angioplasties without open heart backup for patients accepted into the study.

**RULES
OF
DEPARTMENT OF COMMUNITY HEALTH**

**111-2
HEALTH PLANNING**

**111-2-2
Certificate of Need**

111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services.

(1) Applicability.

(a) For Certificate of Need (CON) purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center (DTRC). A certificate of need will be required prior to the establishment of a new or expanded adult cardiac catheterization service.

(b) If the services will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of 111-2-2-.21(3)(f)3 shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in 111-2-2-.21(3)(f)3.

(2) Definitions.

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

21 patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively
22 without the use of motorized vehicles.

23 (b) "Adult" means a person 15 years of age and over.

24 (c) "Authorized service" means an adult cardiac catheterization service that is either
25 existing or approved. An existing service is an authorized service that has become
26 operational, and an approved service is an authorized service that has not yet become
27 operational.

28 (d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per
29 dedicated and multipurpose room per year. In the computation of the use rate (percent
30 of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic
31 cardiac catheterization and other cardiac catheterizations of similar complexity shall
32 equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5
33 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0
34 procedure equivalents. If pediatric catheterizations are performed in a room in which
35 adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0
36 procedure equivalents.

37 (e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure
38 during which a catheter is inserted into a vein or artery in the patient; subsequently, the
39 free end of the catheter is manipulated by the physician to travel along the course of the
40 blood vessel into the chambers or vessels of the heart. X-rays and an electronic image
41 intensifier are used as aids in placing the catheter tip in the desired position. When the
42 catheter is in place, the physician is able to perform various diagnostic studies and/or
43 therapeutic procedures on the heart or its vessels.

44 (f) "Cardiac catheterization service" means an organized program which serves
45 inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and
46 rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

47 angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization
48 procedures. An authorized adult cardiac catheterization service is prohibited from
49 performing coronary angioplasty procedures unless the acute care hospital where the
50 service is located meets the requirements identified in 111-2-2-.21(3)(f)

51 (g) "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary
52 artery disease by utilizing a catheter with a balloon, laser, laser-assisted device,
53 rotational device, stent placement or other mechanical means to unblock an occluded
54 coronary artery.

55 (h) "Diagnostic cardiac catheterization" means the performance of cardiac
56 catheterization for the purpose of detecting and identifying defects in the great arteries or
57 veins of the heart, or abnormalities in the heart structure, whether congenital or
58 acquired. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves
59 or vein grafts) also can be accomplished through use of diagnostic cardiac
60 catheterization.

61 (i)"Diagnostic, treatment, or rehabilitation center (DTRC)" means any professional or
62 business undertaking, whether for profit or not for profit, which offers or proposes to offer
63 any clinical health service in a setting that is not part of a hospital.

64 (j) "Expanded Service" or "Expansion" means an adult cardiac catheterization service
65 that undertakes any capital renovation or construction project in and to the physical
66 space within the hospital where the cardiac catheterization services are or will be
67 offered, the cost of which exceeds the capital expenditure threshold at that time; or that
68 acquires a piece of diagnostic or therapeutic equipment with a value above the
69 equipment threshold at that time which is to be utilized in the provision of cardiac
70 catheterization services; or that seeks the addition of a new catheterization laboratory or
71 room regardless of cost. Replacement or repair of existing diagnostic or therapeutic

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

72 equipment utilized in the provision of such services is not an expansion for purposes of
73 these Rules.

74 (k) "Horizon year" means the last year of a five-year projection period for need
75 determinations for any adult cardiac catheterization services.

76 (l) "Official inventory" means the Department's inventory of all authorized hospital-based
77 and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization
78 laboratories or any other authorized laboratory approved for operation at the time of
79 adoption of these Rules.

80 (m) "Official state component plan" means the document related to specialized
81 cardiovascular services developed by the Department adopted by the Health Strategies
82 Council and approved by the Board of Community Health.

83 (n) "Procedure" means a cardiac catheterization study or treatment or combination of
84 studies and/or treatments performed in a single session on a single patient who appears
85 for cardiac catheterization.

86 (o) "Planning area" means each of the planning areas designated in the official State
87 Component Plan.

88 (p) "Therapeutic cardiac catheterization" means the performance of cardiac
89 catheterization for the purpose of ameliorating certain conditions that have been
90 determined to exist in the heart or great arteries or veins of the heart.

91 **(3) Standards.**

92 (a) The need for new or expanded adult cardiac catheterization services shall be
93 determined through application of a numerical need method and an analysis of service
94 demand based on an assessment of the aggregate utilization rate of existing services;

95 1. the numerical need for new or expanded adult cardiac catheterization services
96 shall be determined by a population-based formula which includes current usage
97 patterns and projected population as follows:

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

- 98 (i) calculate the current state adult cardiac catheterization rate for the most
99 recent year of reported survey or hospital and outpatient discharge data by
100 dividing the total number of adult cardiac catheterizations performed on
101 Georgia residents by the total state adult Resident population;
- 102 (ii) determine the projected adult cardiac catheterization procedures for the
103 horizon year by multiplying the state rate by the adult Resident population for
104 the planning area for the horizon year;
- 105 (iii) adjust the projected adult cardiac catheterization procedures for the
106 planning area by adding the out-of-state hospital-based catheterizations for the
107 most recent year based on the percentage of total procedures performed on
108 out-of-state patients by hospitals in each planning area;
- 109 (iv) convert projected adult cardiac catheterization procedures to procedure
110 equivalents by multiplying the projected procedures by the statewide rate of
111 equivalents per catheterization; and
- 112 (v) determine the projected net surplus or deficit for adult cardiac
113 catheterization capacity, expressed in terms of rooms/laboratories, in the
114 planning area by subtracting the rooms/laboratories needed for the total
115 projected procedure equivalents calculated in steps (i) through (iv) from the
116 total capacity (1300 procedure equivalents per room/laboratory) based on the
117 official inventory.
- 118 2. before a new or expanded adult cardiac catheterization service will be approved
119 in any planning area, the aggregate utilization rate of all adult cardiac
120 catheterization services in that planning area shall be 85 percent or more during
121 the most recent year;
- 122 (b) 1. The Department may allow an exception to 111-2-2-.21(3)(a) in the following
123 circumstances:

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(i) actual utilization in the applicant's existing service has exceeded 90 percent of capacity over the past two years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected

150 through death and hospital discharge data which is significantly higher
151 than the state rate (two or more standard deviations from the mean),
152 and other demographic risk factors which can be documented through
153 research and clinical studies.

154 (V) An applicant seeking approval for a new or expanded adult cardiac
155 catheterization service solely for the purpose of providing cardiac
156 electrophysiological studies may apply for consideration under the
157 terms of an atypical barrier; provided, however, that any such applicant
158 if approved shall be restricted to the provision of electrophysiological
159 studies.

160 2. The Department may allow an exception to 111-2-2-.21(3)(a) and (3)(c) for any
161 cardiac catheterization service seeking an expansion, other than the addition of
162 another laboratory or room; provided the applicant complies with the general
163 considerations and policies of 111-2-2-.09 and submits an application that
164 demonstrates the applicant's compliance with or documents a plan and agreement
165 to comply with 111-2-2-.21(3)(d), (e), (f), (g), (h), (j), (k) and (l).

166 (c) An applicant for a new or expanded adult cardiac catheterization service shall
167 document that authorized cardiac catheterization services which could be adversely
168 impacted by the establishment of the new or expanded service are not predicted to
169 perform less than 80 percent of capacity as a result of the establishment of the new or
170 expanded service. In the case of an approved service, service volume should be
171 projected in accordance with the volume projections in the approved application.

172 (d) An applicant for a new or expanded adult catheterization service shall demonstrate a
173 plan whereby the service and its medical staff agree to provide a full array of
174 cardiovascular services to the community, including, but not limited to, education and
175 outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

176 (e) An applicant for a new or expanded adult cardiac catheterization services shall:

177 1. demonstrate the ability to meet the optimal clinical and physical environment
178 standards established in the most recent American College of Cardiology/American
179 Heart Association's Guidelines for Cardiac Catheterization and Cardiac
180 Catheterization Laboratories. These standards include, but are not limited to,
181 physical facility requirements, staffing, training, quality assurance, patient safety,
182 screening patients for appropriate settings, and linkages with supporting
183 emergency services;

184 2. document the availability of, or shall present a plan for recruiting, at least two
185 board-certified cardiologists with training and qualification in cardiac
186 catheterization, and, if applicable with training and qualification in coronary
187 intervention, who will reside within a one hour drive of the service site; and

188 3. document a plan for obtaining a sufficient number of clinical, professional and
189 technical staff to safely and effectively operate the service.

190 (f) An authorized adult cardiac catheterization service shall not perform catheterization
191 procedures requiring open heart surgery backup as part of its service unless the acute
192 care hospital where the service is located:

193 1. operates an existing adult open heart surgery service;

194 2. has a Department approved written agreement for open heart surgery backup
195 with an adjacent acute care hospital as defined by these Rules; or

196 3. has been accepted as a participant in a randomized medical research trial
197 comparing patient outcomes after non-primary Percutaneous Coronary Intervention
198 (PCI) in hospitals with and without cardiac surgery on-site, which also requires the
199 performance of Primary PCI and has a parallel Primary PCI Registry, and which is
200 coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team
201 (Atlantic C-PORT). The authorized adult cardiac catheterization service must

202 receive such Atlantic C-PORT acceptance and also must obtain written approval
203 from the Department to perform such procedures, except that the Department may
204 approve no more than ten (10) existing and authorized hospital services for
205 participation, regardless of the number of such services that are accepted by Atlantic
206 C-PORT.

207 (i) Any request for such Departmental approval must be submitted to the
208 Department no later than June 30, 2005 in writing on a form developed by
209 the Department for such purposes. Prior to final approval to participate by
210 the Department, the requesting authorized service must provide written
211 proof it has been accepted by Atlantic C-PORT as a participant in said trial
212 under all applicable protocols;

213 (ii) In reviewing and approving such requests, the Department shall take into
214 consideration such factors including, but not limited to, rural, suburban or
215 urban location of the service, mix of patients to be treated, whether the
216 service has the capability of performing a minimum of 100 PCIs (elective
217 and primary combined) during the first year of such approval, 200 PCIs
218 (elective and primary combined) during the second year of such approval
219 unless a lower number, but not below 150 PCIs, is approved for specific
220 reasons by both the Department and the trial chairperson, and 200 PCIs
221 (elective and primary combined) during the third year of such approval, and
222 whether the service has on its staff physicians and support staff with
223 training and experience in both therapeutic and diagnostic cardiac
224 catheterizations;

225 (iii) The selection of an authorized service for participation pursuant to this rule
226 will be made at the sole discretion of the Department; however, the
227 Department shall consult with medical experts in the fields of cardiology

228 and percutaneous coronary intervention when making the decision to
229 approve or not approve a particular service for participation in such trial;
230 (iv) Any approval obtained from the Department in this regard shall only be
231 valid for as long as the health care facility receiving such approval is an
232 active participant in the trial; however, in no case shall such approval
233 continue to be valid upon Atlantic C-PORT declaring the trial concluded, or
234 under no circumstance for a period in excess of three years from the time
235 the authorized service's first procedure is conducted under the authority of
236 the Department's approval and Atlantic C-PORT's acceptance to begin
237 active participation in the trial; whichever event occurs first; and
238 (v) As any such Departmental approval is conditioned on being an active
239 participant in the trial, should an authorized service which has received
240 approval under the provisions of this rule be expelled or otherwise lose the
241 approval of Atlantic C-PORT to continue participation, the Department's
242 approval will be simultaneously withdrawn without said service's or facility's
243 right to an appeal of the Department's withdrawal of its approval to
244 participate in such trial.

245 (g) Catheterization procedures requiring open heart surgery backup include coronary
246 angioplasty and the following:

- 247 1. catheter atherectomy;
- 248 2. catheter endomyocardial biopsy;
- 249 3. left ventricular puncture;
- 250 4. percutaneous transluminal coronary angioplasty;
- 251 5. percutaneous catheter balloon valvuloplasty; and
- 252 6. transeptal catheterization.

253 (h) An applicant for a new or expanded adult cardiac catheterization service shall:

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

254 1. submit a written plan to the Department which, when implemented, will ensure
255 access to cardiac catheterization services for all segments of the population in the
256 documented and proposed service area of the applicant. Such plan shall provide a
257 detailed strategy to reach patients not currently served within the service area,
258 ensure continuity of care for patients transferred between facilities and shall
259 promote planning for a continuum of cardiac services within the service area; and
260 2. propose a heart disease prevention and clinical intervention program to be
261 provided by the applicant or through formal referral agreements which, when
262 implemented, shall include:

263 (i) A clinical intervention program for all catheterization patients that shall
264 provide for the following in a comprehensive, systematic way:

265 (I) Assessment of risk factors including lipid disorders, hypertension,
266 diabetes, obesity, cigarette smoking, and sedentary lifestyle;

267 (II) Assessment of risk factors and referral for appropriate care in first-
268 degree relatives; and

269 (III) Assure risk management including modification of lipid disorders by
270 diet/exercise/drugs, modification of blood pressure level by
271 diet/exercise/drugs, control of blood glucose level by
272 diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat
273 intake and appropriate weight management, smoking cessation, and
274 exercise prescription. Patients should be referred to their primary care
275 provider with documentation of treatments provided and actions
276 recommended including preventive therapies.

277 (ii) The program, if not operated by a facility with an existing Open Heart
278 Surgical Service, shall submit a written affiliation agreement with at least one
279 Open Heart Surgical Service that provides, at a minimum, for:

- 280 (I) a plan to transport and handle acute cardiac emergencies;
- 281 (II) a plan to facilitate referral of patients for whom surgery or
- 282 angioplasty may be indicated without unnecessarily repeating
- 283 diagnostic studies; and
- 284 (III) a plan for ongoing communications between representatives of the
- 285 Open Heart Surgical Service and the proposed applicant, to allow for
- 286 review of pre-operative and post-operative processes and specific
- 287 cases.
- 288 (iii) The program shall provide for annual support and participation in at least
- 289 three professional education programs targeted to community based health
- 290 professionals, related to heart disease risk assessment, diagnostic procedures,
- 291 disease management in clinical settings, and case finding and referral
- 292 strategies.
- 293 (iv) Community based heart health promotion:
- 294 (I) The program shall provide for organization of or participation in a
- 295 consortium of community-based organizations to complete an
- 296 assessment of heart disease risk factors in the community as well as
- 297 resources available to provide programs and services. The objective of
- 298 this consortium is to mobilize and coordinate resources to target at-risk
- 299 populations in the community; and
- 300 (II) Organization of or participation in at least one major community-
- 301 based campaign each year related to major heart disease risk factors.
- 302 3. propose a system of outcome monitoring and quality improvement and identify
- 303 at least five clinical outcomes that the applicant proposes to monitor for
- 304 performance on a regular basis.

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

305 (i) An applicant for a new or expanded adult cardiac catheterization service must project
306 and, if approved, shall document that the proposed service will be performing a minimum
307 of 1040 adult cardiac catheterization procedure equivalents within three years of
308 initiation of the service and annually thereafter within the authorized guidelines for such
309 services. Such projections, at a minimum, shall include consideration of patient origin
310 data for catheterization services, the use rate of existing services, referral data and
311 market patterns for existing hospital and DTRC services in the community, and
312 cardiovascular disease incidence rates and related health indicators. An applicant
313 seeking approval solely for the purpose of providing electrophysiological (EP) studies
314 shall not be required to document a projected performance minimum but shall be
315 required to document compliance with guidelines for EP studies issued by the American
316 College of Cardiology

317 (j) An applicant for a new or expanded adult cardiac catheterization service shall provide
318 documentation that the service is fully accredited by the Joint Commission on
319 Accreditation of Health Care Organizations (JCAHO) or, in the case of an applicant
320 proposing a new facility location, shall provide a written commitment to secure full
321 accreditation by JCAHO within eighteen (18) months of initiating operation.

322 (k) An applicant for a new or expanded adult cardiac catheterization service shall foster
323 an environment that assures access to individuals unable to pay, regardless of payment
324 source or circumstances, by the following:

- 325 1. providing a written policy regarding the provision of any services provided by or
326 on behalf of the applicant to include disease prevention and intervention services
327 outlined in 111-2-2-.21(3)(h), that such services shall be provided regardless of
328 race, age, sex, creed, religion, disability or patient's ability to pay, and
329 documentation or evidence that the applicant has a service history reflecting the
330 principles of such a policy; and

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

331 2. providing a written commitment that services for indigent and charity patients will
332 be offered at a standard which meets or exceeds three percent of annual, adjusted
333 gross revenues for the adult cardiac catheterization service, or the applicant may
334 request that the Department consider allowing the commitment for services to
335 indigent and charity to patients to be applied to the entire facility;

336 3. providing a written commitment to accept any patient within the facility's service
337 area, without regard to the patient's ability to pay, unless such patient is clinically
338 inappropriate;

339 4. providing a written commitment to participate in the Medicaid, Peach Care and
340 Medicare programs and to accept any Medicaid-, Peach Care- and/or Medicare-
341 eligible patient for services unless such patient is clinically inappropriate;

342 5. providing a written commitment that the applicant, subject to good faith
343 negotiations, will participate in any state health benefits insurance programs for
344 which the service is deemed eligible; and

345 6. providing documentation of the past record of performance of the applicant, and
346 any facility in Georgia owned or operated by the applicant's parent organization, of
347 providing services to Medicare, Medicaid, and indigent and charity patients. The
348 applicant's or its parent organization's failure to provide services at an acceptable
349 level to Medicare, Medicaid and indigent and charity patients, and/or the failure to
350 fulfill any previously made commitment to indigent and charity care may constitute
351 sufficient justification to deny the application.

352 (l) An applicant for a new or expanded adult cardiac catheterization service must agree
353 in writing to the following conditions:

354 1. establishment and maintenance of a system of continuity of care and
355 coordination of service, as evidenced by regular and ongoing planning and quality
356 improvement sessions with community health providers and advocacy programs;

**CERTIFICATE OF NEED
As Adopted by the HSC on February 4, 2005**

111-2-2

357 2. participation in a data reporting, quality improvement, outcome monitoring, and
358 peer review system within the applicant hospital or DTRC as well as a national,
359 state or multi-program system which benchmarks outcomes based on national
360 norms and which shall be named in the application and which provides for peer
361 review between and among professionals practicing in facilities and programs
362 other than the applicant hospital or DTRC;

363 3. development of procedures to ensure that cardiologists and any other physicians
364 providing care in the cardiac catheterization service or related services shall be
365 required to accept Medicaid, Peach Care and Medicare payment for services
366 without discrimination;

367 4. commitment that charges for services shall be reasonable and comparable to
368 other providers in the state and the service area;

369 5. provision of all required data and survey information to the Department as
370 requested; and

371 6. commitment to act in good faith to fulfill all provisions and commitments
372 documented in the application for a new or expanded service.

373 (m) The department may revoke a Certificate of Need after notice to the holder of the
374 certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for
375 failure to comply with the defined scope, location, cost, service area, and person named
376 in an application as approved by the Department and for the intentional provision of false
377 information to the Department by an applicant in that applicant's application.