

## **SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS**

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**SECTION .1100 – GENERAL INFORMATION: DEFINITIONS**

### **10A NCAC 14F .1101 DEFINITIONS**

The following definitions shall apply throughout this Subchapter:

- (1) "ACLS-trained" means training that is current in Advanced Cardiac Life Support, by the American Heart Association and who has appropriate licensure to administer advanced cardiac life support.
- (2) "ACSM" means the American College of Sports Medicine.
- (3) "Article" means Article 8 of G.S. 131E.
- (4) "Cardiac Rehabilitation Program" has the same meaning as the definition in the Article.
- (5) "Certification" has the same meaning as the definition in the Article.
- (6) "DVRs" means the Division of Vocational Rehabilitation Services, North Carolina Department of Health and Human Services.
- (7) "Department" means the North Carolina Department of Health and Human Services.
- (8) "Division" means the Division of Health Service Regulation, North Carolina Department of Health and Human Services.
- (9) "ECG" means electrocardiogram.
- (10) "Graded exercise test" (GXT) means a multistage test that determines a person's physiological response to different intensities of exercise or the person's peak aerobic capacity.
- (11) "Maximal oxygen consumption" means the highest rate of oxygen transport and oxygen use that can be achieved at a person's maximal physical exertion, or functional capacity. This is usually expressed in METs.
- (12) "MET" means "metabolic equivalent," a measure of functional capacity, or maximal oxygen consumption. One MET represents the approximate rate of oxygen consumption by a seated individual at rest: approximately 3.5 ml/kg/min. METs during exercise are determined by dividing metabolic rate during exercise by the metabolic rate at rest.
- (13) "Nurse Practitioner" means a currently licensed registered nurse approved by the NC Board of Nursing and NC Medical Board to practice medicine as a nurse practitioner under the supervision of a physician licensed by the Board.
- (14) "Owner" means the legal owner of the certified cardiac rehabilitation program.
- (15) "Physician" means an individual who is licensed according to G.S. 90, Article 1, by the NC Medical Board to practice medicine.
- (16) "Physician Assistant" means an individual who is licensed and registered according to G.S. 90, Article 1, by the NC Medical Board to practice medicine under the supervision of a physician licensed by the Board.
- (17) "Premises" means "site."

- (18) "Program" means "Cardiac Rehabilitation Program."
- (19) "Risk stratification model" means a method of categorizing patients according to their risk of acute cardiovascular complications during exercise as well as their overall prognosis. Risk status is related primarily to the type and severity of cardiovascular disease. This rating takes into account how well the heart pumps, the presence of heart pain symptoms and/or changes in the electrocardiogram during exercise. Guidelines concerning medical supervision of patients in cardiac rehabilitation programs which are based on risk stratification models are provided by: the American College of Cardiology, the American College of Physicians, the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the North Carolina Cardiopulmonary Rehabilitation Association.
- (20) "Simple spirometry" means an analysis of air flow which provides information as to the degree and severity of airway obstruction, and serves as an index of dynamic lung function. It must include, at a minimum, Forced Vital Capacity and Forced Expiratory Volume in 1 second.
- (21) "Site" means the facility in which the cardiac rehabilitation program is held.
- (22) "Supervising physician" means a physician who is on-site during the operation of the cardiac rehabilitation program.
- (23) "Symptom-limited heart rate reserve" means the difference between the symptom-limited maximal heart rate and the resting heart rate.
- (24) "Vocational Questionnaire" means the document used for vocational assessment.
- (25) "Vocational Rehabilitation Counselor" means an individual who provides vocational rehabilitation counseling services.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

## **SECTION .1200 – CERTIFICATION**

### **10A NCAC 14F .1201 CERTIFICATE**

The named person(s) and the street address of the named premises shall appear on the certificate.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

### **10A NCAC 14F .1202 CERTIFICATION PROCESS**

(a) To initiate the certification process, an application for certification shall be filed with the Department by the owner of the cardiac rehabilitation services.

(b) Application forms shall be available from the Department, and each application shall contain at least the following information:

- (1) legal identity of the owner-applicant;
- (2) name or names under which the facility or services are advertised or presented to the public;
- (3) program mailing address;
- (4) program exercise site;
- (5) program telephone number;
- (6) ownership disclosure;
- (7) name of program director;
- (8) name of medical director; and
- (9) program hours of operation.

(c) No applicant shall offer any cardiac rehabilitation services described or represented as a "Certified Cardiac Rehabilitation Program," unless the services have been certified in accordance with the provisions of this Subchapter.

(d) Except as otherwise provided in this Section, the Department shall inspect and evaluate the program and premises identified in the application and shall thereafter issue a certificate upon its determination that the applicant has substantially complied with, and the program and the services at the premises substantially met, the provisions of the Article and this Subchapter.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

### **10A NCAC 14F .1203 CERTIFICATE RENEWAL**

(a) A certificate issued pursuant to the Article and this Subchapter shall expire two years after the effective date but can be renewed upon the successful re-evaluation of the program. To initiate the renewal process, an application for certification shall be filed with the Department by the owner of the program.

(b) Determination of compliance with the provisions of the Article and this Subchapter for purposes of certificate renewal may, at the discretion of the Department, be based upon an inspection or upon review of requested information submitted by a program to the Department.

*History Note: Authority G.S. 131E-167; 131E-169;  
Eff. July 1, 2000.*

### **10A NCAC 14F .1204 CERTIFICATION FOLLOWING PROGRAM CHANGES**

(a) The Department shall be notified, in writing, at least 30 days prior to the effective date, of any expected occurrences of the following:

- (1) change in program ownership;
- (2) change in program name;
- (3) change of the premises in which a program is conducted; and
- (4) the replacement or termination of employment of the program director.

(b) If a 30-day advanced written notification of any occurrence enumerated in Paragraph (a) of this Rule is not possible, the Department shall be notified immediately, by any reasonably reliable means of notification, of such expected or completed occurrence, and written notification shall follow immediately thereafter.

(c) Upon the occurrences enumerated in Subparagraphs (a)(1), (2), and (3) of this Rule, the owner of the program shall file with the Department an application for certification, which, at a minimum, shall contain the information specified in Rule .1202(b) of this Subchapter, and shall provide such other documentation and information as requested by the Department.

(d) The revised program shall be evaluated for compliance with the provisions of the Article and this Section. Evaluation may be based upon inspection of the program or upon review of requested information submitted by a program to the Department. After a determination by the Department that the program substantially complies with the provisions of the Article and this Subchapter, a new certificate shall be issued.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

### **10A NCAC 14F .1205 INSPECTIONS**

(a) In accordance with G.S. 131E-167(c), inspection(s) shall be made by the Department before a program is issued its initial certification as a program defined in the Article.

(b) The Department shall make or cause to be made such other inspections of a program as it deems necessary in accordance with the Article. Circumstances which may be deemed to necessitate an inspection include, but are not limited to:

- (1) change in program ownership;
- (2) change in program name;
- (3) change of the premises in which a program is conducted;
- (4) the replacement or termination of employment of the program director; and
- (5) investigation of complaints.

(c) Inspections shall be announced or unannounced and may be conducted any time during program business hours. The purpose of any inspection shall be discussed with the Program Director or designee during an entrance conference.

(d) Information deemed necessary by the Department to evaluate compliance with the Article and this Subchapter, shall be made available for inspection. The information may include medical records, personnel files, policies and procedures, program records, interviews with program staff, interviews with patients, observation of the program in operation, and any other information necessary to determine compliance.

(e) Following completion of an inspection, an exit conference shall be conducted with one or more representatives of the program's management. An oral summary of the findings shall be presented at the exit conference. The Department shall provide the program with a written report of the findings. The program shall have 10 working days from the receipt of the report to respond with a plan of correction which describes the corrective actions planned and taken to correct any cited deficiency(ies), the date each deficiency was or will be corrected, and the date the program expects to be in compliance with the provisions of the Article and this Subchapter.

*History Note: Authority G.S. 131E-169; 131E-170;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1206 ADVERSE ACTION**

(a) Upon a determination that there has been a substantial failure to comply with the provisions of the Article or the rules contained in this Subchapter, the Department may, at its discretion, deny a new or renewal certificate, suspend or revoke an existing certificate, or, as enumerated in Paragraph (c) of this Rule, issue a provisional certificate.

(b) Substantial noncompliance which has endangered, or has a potential to endanger the health, safety, or welfare of any patient, shall be cause for the denial, revocation, or suspension of a certificate.

(c) Substantial noncompliance which does not endanger the health, safety, or welfare of the patients being served may, at the discretion of the Department, result in the issuance of a provisional certificate for a period not to exceed six months.

*History Note: Authority G.S. 131E-168; 131E-169;  
Eff. July 1, 2000.*

### **SECTION .1300 – ADMINISTRATION**

#### **10A NCAC 14F .1301 STAFF REQUIREMENTS AND RESPONSIBILITIES**

(a) Each program shall be conducted utilizing an interdisciplinary team composed of a program director, medical director, nurse, exercise specialist, mental health professional, dietician or nutritionist, supervising physician, physician assistant or nurse practitioner, and a DVRS or other vocational rehabilitation counselor. The program may employ, full-time or part-time, or contract for the services of team members. Program staff shall be available to patients as needed to perform initial assessments and to implement each patient's cardiac rehabilitation care plan.

(b) Individuals may perform multiple team functions, if qualified for each function, as stated in this Rule:

- (1) Program Director - supervises program staff and directs all facets of the program.
- (2) Medical Director B physician who provides medical assessments and is responsible for supervising all clinical aspects of the program and for assuring the adequacy of emergency procedures and equipment, testing equipment, and personnel.
- (3) Nurse - provides nursing assessments and services.
- (4) Exercise Specialist - provides an exercise assessment, in consultation with the medical director, plans and evaluates exercise therapies.
- (5) Mental Health Professional - provides directly or assists program staff in completion of the mental health screening and referral, if indicated, for further mental health services.
- (6) Dietitian or Nutritionist - provides directly or assists program staff in completion of the nutrition assessment and referral, if indicated, for further nutrition services.
- (7) Supervising Physician, Physician Assistant, or Nurse Practitioner - medical person who is on-site during the operation of programs that are not located within a hospital.
- (8) DVRS or other Vocational Rehabilitation Counselor - screens patients who may be eligible for and interested in vocational rehabilitation services, develops assessment and intervention strategies, and provides other services as needed to meet the vocational goal(s) of patients who may be eligible for and interested in services.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1302 POLICIES AND PROCEDURES**

The program director shall assure that written policies and procedures are adopted by the program, approved by the medical director, and available to and implemented by staff. At a minimum, these policies and procedures shall include the following areas:

- (1) admission of patients and orientation to the program;
- (2) patient assessment, care planning, and implementation of therapies;
- (3) patient follow-up evaluations, including progress toward cardiac rehabilitation goals;
- (4) patient discharge;
- (5) medical records, in accordance with Rule .2002 of this Subchapter;

- (6) orientation of all program personnel;
- (7) maintenance of personnel records which include job descriptions, verification of credentials, continuing education and current competencies;
- (8) use and orientation of volunteers;
- (9) communication with patient's referral and personal physicians;
- (10) provisions for reporting and investigating complaints and accidental events regarding patients, visitors and personnel (incidents) and corrective action taken;
- (11) emergency procedures;
- (12) a preventative maintenance program to assure all equipment is maintained in safe and proper working order and in accordance with the manufacturer's recommendations; and
- (13) quality improvement program.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

### **10A NCAC 14F .1303 CONTINUOUS QUALITY IMPROVEMENT**

- (a) The cardiac rehabilitation program shall have an ongoing Continuous Quality Improvement (CQI) program which identifies quality deficiencies and addresses them with corrective plans of action, as indicated.
- (b) The CQI program shall evaluate the appropriateness, effectiveness, and quality of the cardiac rehabilitation program, with findings used to verify policy implementation, to identify problems, and to establish problem resolution and policy revision as necessary.
- (c) The CQI program shall consist of an overall policy and administration review, including admission and discharge policies, emergency care, patient records, personnel qualifications and program evaluation. Data to be assessed shall include, at a minimum, the following:
  - (1) number of patients in the program;
  - (2) average length (weeks) patients are in the program;
  - (3) patient clinical outcomes;
  - (4) adequacy of staff to meet program/patient needs;
  - (5) reasons for discharge; and
  - (6) untoward events.
- (d) A sample of active and closed records shall be reviewed at least semi-annually to assure program policies are followed and the program is in compliance with the Article and the rules contained in this Subchapter.
- (e) Documentation of the CQI program shall include the criteria and methods used to collect and analyze data, identification of quality deficiencies, and any action(s) taken by the cardiac rehabilitation program as a result of CQI findings.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

## **SECTION .1400 – PATIENT RIGHTS**

### **10A NCAC 14F .1401 PATIENT RIGHTS**

- (a) Prior to or at the time of admission, the program shall provide each patient with a written notice of the patient's rights and responsibilities. The program shall maintain documentation showing that all patients have been informed of their rights and responsibilities.
- (b) Each patient's rights shall include, at a minimum, the right to:
  - (1) be informed and participate in developing the patient's plan of care;
  - (2) voice grievances about the care provided, and not be subjected to discrimination or reprisal for doing so;
  - (3) confidentiality of the patient's records;
  - (4) be informed of the patient's liability for payment for services;
  - (5) be informed of the process for acceptance and continuation of service and eligibility determination;
  - (6) accept or refuse services; and
  - (7) be advised of the program's procedures for discharge.
- (c) The program shall provide all patients with a telephone number for information, questions or complaints about services provided by the program. The program shall also provide the Division Complaints Hotline number or the Department of Health and Human Services Careline number or both.

(d) The program shall investigate, within seven days, complaints made to the program by the patient, the patient's family, or significant other, and must document both the existence of the complaint and the resolution of the complaint.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

## **SECTION .1500 – ADMISSION AND DISCHARGE**

### **10A NCAC 14F .1501 ADMISSION AND DISCHARGE**

- (a) All patients admitted to the program shall have a referral from a physician.
- (b) Prior to discharging a patient, the interdisciplinary team shall develop a discharge plan. At a minimum, the discharge plan shall include instructions as to how to achieve or maintain the goals established in the cardiac rehabilitation care plan.
- (c) Upon discharge from the program, a discharge summary as outlined in Rule .2002(a)(10) of this Subchapter, shall be sent to the personal or referring physician.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

## **SECTION .1600 – PATIENT ASSESSMENT**

### **10A NCAC 14F .1601 PATIENT ASSESSMENT**

- (a) Within five weeks of a patient's admission to the program, the interdisciplinary team shall complete and document a cardiac rehabilitation assessment. At a minimum, the assessment shall include the components specified in this Rule.
- (b) Medical Assessment shall include:
  - (1) cardiovascular evaluation as to present diagnosis, therapy, and a discharge summary of the patient's last hospitalization; or
  - (2) statement by referring physician as to present diagnosis, and therapy;
  - (3) resting 12-lead ECG;
  - (4) medical record documentation prior to or during the first exercise session of ECG, hemodynamic data, and the presence or absence of symptoms, preferably determined by a graded exercise test. A graded exercise test shall not be required when deemed unnecessary by the patient's attending or personal physician or the program's medical director;
  - (5) fasting blood chemistry, as indicated, to include total cholesterol, high density lipoprotein (HDL) cholesterol, low density lipoprotein (LDL) cholesterol, triglycerides, and other comparable measures; and
  - (6) simple spirometry, if clinically indicated.
- (c) Physical Assessment shall include:
  - (1) functional capacity as determined by measured or predicted equivalents (METs);
  - (2) height, weight, or other anthropometric measures (i.e., body mass index, percent body fat, waist-to-hip ratio, girth measurements);
  - (3) current and past exercise history; and
  - (4) physical limitations and disabilities that may impact rehabilitation.
- (d) Nursing Assessment shall include:
  - (1) coronary risk profile;
  - (2) current symptoms such as angina or dyspnea, and recovery from recent cardiac events;
  - (3) presence of comorbidities;
  - (4) assessment of medications; and
  - (5) educational needs.
- (e) Nutrition Assessment shall include:
  - (1) review of medical history;
  - (2) eating patterns as measured by a food diary or food frequency questionnaire;
  - (3) fasting blood chemistries as described in Subparagraph (b)(5) of this Rule;
  - (4) anthropometric measures as described in Subparagraph (c)(2) of this Rule;
  - (5) behavioral patterns; and
  - (6) identification of nutritional goals.
- (f) Mental Health Assessment shall include:

- (1) past history of mental illness including depression, anxiety, or hostility or anger; and
  - (2) present mental health functioning and need for referral to a mental health professional.
- (g) Vocational Assessment shall include:
- (1) vocational questionnaire to determine current vocational status, description of physical requirements of job, working conditions, psychological demands as perceived by the patient; and
  - (2) the need for vocational rehabilitation services.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

## **SECTION .1700 – CARE PLANNING AND FOLLOW-UP EVALUATION**

### **10A NCAC 14F .1701 CARE PLANNING**

- (a) Within five weeks of a patient's admission to the program, the interdisciplinary team shall develop a cardiac rehabilitation care plan for the patient based upon assessments completed as required under Section .1600 of this Subchapter.
- (b) The cardiac rehabilitation care plan, at a minimum, shall include:
- (1) the patient's exercise therapy;
  - (2) nutrition services, if indicated;
  - (3) mental health services, if indicated;
  - (4) vocational services if, indicated;
  - (5) educational counseling;
  - (6) cardiac rehabilitation goals; and
  - (7) discharge planning.
- (c) Within six weeks of the patient's admission to the program, a copy of the cardiac rehabilitation care plan shall be sent to the patient's personal and referring physicians.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

### **10A NCAC 14F .1702 FOLLOW-UP EVALUATION**

- (a) The interdisciplinary team members shall attend monthly meetings for follow-up evaluation of patients' progress toward cardiac rehabilitation goals. Changes to each patient's cardiac rehabilitation care plan shall be made as needed based on continued evaluations. Any changes made in the patient's cardiac rehabilitation care plan shall be recorded in the medical record and sent to the patient's personal and referring physician(s).
- (b) If any staff member cannot attend, the reason for the absence and the means of communicating information prior to and after the meeting shall be documented.
- (c) The personal and referring physician(s) shall be informed of any complication or change in patient status while in the program.
- (d) Progress notes shall be recorded in the patient's medical record evaluating progress toward goals established from the plan of care.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

## **SECTION .1800 – PROVISION OF SERVICES**

### **10A NCAC 14F .1801 PERSONNEL**

- (a) At least one ACLS trained and one other staff member shall be present at the site during all program hours.
- (b) For cardiac rehabilitation programs that are not located within a hospital or a hospital emergency resuscitation team is not available to respond in an emergency, a supervising physician, physician assistant, or nurse practitioner shall be on-site during all program hours.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1802 EXERCISE THERAPY**

(a) The medical director, in consultation with program staff, shall establish staff to patient ratios for exercise therapy sessions based on medical acuity, utilizing an acceptable risk stratification model.

(b) If any patient has not had a graded exercise test prior to the first exercise session, the patient's first exercise session must include objective assessment of hemodynamic data, ECG, and symptom response data.

(c) Unless contraindicated by medical and laboratory assessments or the cardiac rehabilitation care plan, each patient's exercise therapy shall include:

- (1) mode of exercise therapy including, but not limited to: walk/jog, aquatic activity, cycle ergometry, arm ergometry, resistance training, stair climbing, rowing, aerobics;
- (2) intensity:
  - (A) up to 85 percent of symptom-limited heart rate reserve;
  - (B) up to 80 percent of measured maximal oxygen consumption;
  - (C) rating of perceived exertion (RPE) of 11 to 13 if a graded exercise test is not performed; or
  - (D) for myocardial infarction patients: heart rate not to exceed 20 beats per minute above standing resting heart rate if a graded exercise test is not performed; and for post coronary artery by-pass graft patients: heart rate not to exceed 30 beats per minute above standing resting heart rate if a graded exercise test is not performed;
- (3) duration: up to 60 minutes, as tolerated, including a minimum of five minutes each for warm-up and cool-down; and
- (4) frequency: minimum of three days per week.

(d) The patient shall be monitored through the use of electrocardiography during each exercise therapy session. The frequency of the monitoring continuous or intermittent shall be based on medical acuity and risk stratification.

(e) At two week intervals, the patient's adherence to the cardiac rehabilitation care plan and progress toward goals shall be monitored by an examination of exercise therapy records and documented.

(f) The exercise specialist shall be responsible for consultation with the medical director or the patient's personal physician concerning changes in the exercise therapy, results of graded exercise tests, as needed or anticipated (e.g. regular follow-up intervals, graded exercise test conducted, or medication changes). Feedback concerning changes in the exercise therapy shall be discussed with the patient and documented.

(g) Diabetic patients who are taking insulin or oral hypoglycemic agents for control of diabetes shall have blood sugars monitored for at least the first week of cardiac therapy sessions in order to establish the patient's level of control and subsequent response to exercise. Cardiac rehabilitation staff shall record blood sugar measurements pre- and post-exercise. Patients whose blood sugar values are considered abnormal for the particular patient shall be monitored. A carbohydrate food source or serving shall be available. Snacks shall be available in case of a hypoglycemic response.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1803 NUTRITION SERVICES**

If indicated, based on the nutrition assessment and cardiac rehabilitation care plan, each patient's program shall include the following nutrition services:

- (1) interpretation and feedback on the patient's eating patterns, blood chemistries, anthropometrics, and behavioral patterns;
- (2) identification of a therapeutic diet plan to determine, at a minimum, a reasonable body weight, caloric, and fat intake;
- (3) patient counseling or behavior modification based on the therapeutic diet plan and goals.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1804 MENTAL HEALTH SERVICES**

If indicated, based on the mental health assessment and cardiac rehabilitation care plan, each patient's program shall include the following mental health services:

- (1) feedback from mental health assessment to the patient; and
- (2) present mental health functioning and need for referral to a mental health professional for evaluation or treatment.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1805 VOCATIONAL REHABILITATION COUNSELING AND SERVICES**

(a) The cardiac rehabilitation program shall have a written agreement, with the local DVRS office or other vocational rehabilitation counselor/services, which specifies the following:

- (1) The program shall administer a Vocational Questionnaire to patients.
- (2) After administering the Vocational Questionnaire, the program shall refer to the DVRS or other vocational rehabilitation counselor/services patients who may be eligible for and desire services.
- (3) The DVRS or other vocational rehabilitation counselor shall provide feedback to the cardiac rehabilitation program regarding the eligibility for DVRS or other vocational services of referred patients.
- (4) The DVRS or other vocational rehabilitation counselor shall provide progress reports for patients who are receiving DVRS or other vocational rehabilitation services.
- (5) The DVRS or other vocational rehabilitation counselor shall attend monthly staff meetings in which eligible vocational rehabilitation clients are discussed. If the counselor cannot attend, the reason for the absence and the means of communicating information prior to and after the meeting shall be documented and attached to the staffing report.

(b) The cardiac rehabilitation program must have written documentation that feedback as described in Subparagraph (a)(3) of this Rule and progress reports as described in Subparagraph (a)(4) of this Rule have been communicated to the cardiac rehabilitation program by the DVRS or other counselor and, if not, the reason(s) why.

(c) If the program is not able to complete a written agreement with the local office of DVRS or other vocational rehabilitation counselor as outlined in Paragraph (a) of this Rule, the program shall have documentation that specifies why such an agreement was not completed.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1806 PATIENT EDUCATION**

(a) Each patient's cardiac rehabilitation care plan shall include participation in the program's basic education plan. At a minimum, the education plan shall include the following topics:

- (1) basic anatomy, physiology, and pathophysiology of the cardiovascular system;
- (2) risk factor reductions, including smoking cessation and management of blood pressure, lipids, diabetes, and obesity;
- (3) principles of behavior modification including nutrition, exercise, stress management and other lifestyle changes;
- (4) relaxation training offered at least once per week by staff trained in relaxation techniques;
- (5) cardiovascular medications including compliance, interactions, and side effects;
- (6) basic principles of exercise physiology, guidelines for safe and effective exercise therapy, and guidelines for vocational/recreational exertional activities;
- (7) recognition of cardiovascular signs, symptoms and management; and
- (8) environmental considerations such as exercise in hot or cold climates.

(b) The educational program shall include individual or group sessions utilizing written, audio, or visual educational materials as deemed appropriate and necessary by program staff.

(c) Each session shall be documented and presented on a rotating basis such that each patient has access to all materials and classes offered.

(d) Documentation shall be included in each patient's medical record to indicate which educational programs the patient attended.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

### **SECTION .1900 – EMERGENCIES**

#### **10A NCAC 14F .1901 EMERGENCY PLAN**

A written plan approved and signed by the medical director shall be established to handle any emergencies occurring on site while cardiac rehabilitation services are being provided. All areas of the premises pertinent to program operation shall be included. The plan shall address the assignment of personnel and availability of equipment required in an emergency.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1902 EMERGENCY EQUIPMENT**

The following equipment and supplies must be available and operable in the event of an emergency and must be maintained according to manufacturer's recommendations:

- (1) suction equipment (portable);
- (2) defibrillator (portable);
- (3) intubation equipment;
- (4) medications;
- (5) oxygen tank supply;
- (6) regulator and mask for nasal cannula; and
- (7) communication system to access emergency medical services.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .1903 EMERGENCY DRILLS**

- (a) At least six patient emergency drills shall be conducted each year and shall be documented.
- (b) Drill sites shall be rotated through all locations used by patients while participating in program activities.
- (c) The drill documentation and effectiveness of emergency drills shall be reviewed and signed by the medical director or supervising physician.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

### **SECTION .2000 – MEDICAL RECORDS**

#### **10A NCAC 14F .2001 POLICIES AND PROCEDURES FOR MEDICAL RECORDS**

The program shall develop and implement policies and procedures to include at least the following:

- (1) maintenance of a complete, accurate, and organized medical record for each patient admitted to the program;
- (2) confidentiality of records;
- (3) accessibility of medical record information to the patient, program staff, and non-employees; and
- (4) authentication of entries in medical records including hard copy records and those kept in electronic medium such as computerized records.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .2002 CONTENT OF MEDICAL RECORDS**

(a) The medical record shall contain at least the following information:

- (1) patient identification data;
- (2) medical history and, when applicable, hospital discharge summary;
- (3) graded exercise data, if available;
- (4) resting 12-lead ECG;
- (5) signed physician referral;
- (6) records of blood chemistry analyses;
- (7) signed informed consent to participate in the program;
- (8) progress notes and response to the cardiac rehabilitation care plan;
- (9) all records of each discipline's participation in the patient's cardiac rehabilitation care plan;

- (10) a discharge summary which describes the patient's progress while in the program, reason(s) for discharge, the post-discharge plan, and follow-up as indicated;
  - (11) miscellaneous clinical records developed pursuant to the patient's course of treatment.
- (b) In the case of hard copy medical records, the following shall apply:
- (1) the patient's name must be recorded on each page of the record;
  - (2) all entries in the records shall be legible and authenticated with a signature, title, and date by the individual making the entry; and
  - (3) faxed entries, including orders, are acceptable as long as a hard copy is incorporated in the medical record (note: thermal paper faxes are not acceptable).
- (c) At its option, the program may maintain all or part of its medical records in a form other than hard copy, such as electronic medium. Entries in such a record shall be authenticated according to program policies and may include authentication measures such as personal computer entry codes or electronic signatures. However, when requested by the Division or other State officials, the program must be able to produce a hard copy printout of the record.
- (d) Medical record information may be stored, such as when records are thinned or patients are discharged, in a form other than hard copy, but the program must be able to produce a hard copy printout of the record if requested by the Division or other State officials.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

## **SECTION .2100 – FACILITIES AND EQUIPMENT**

### **10A NCAC 14F .2101 PHYSICAL ENVIRONMENT AND EQUIPMENT**

- (a) The program shall provide a clean and safe environment.
- (b) Equipment and furnishings shall be cleaned not less than weekly.
- (c) All areas of the facility shall be orderly and free of debris and with clear traffic areas.
- (d) A written and documented preventative maintenance program shall be established to ensure that all equipment is calibrated and maintained in safe and proper working order in accordance with manufacturers' recommendations.
- (e) There shall be emergency access to all areas a patient may enter, and floor space must allow easy access of personnel and equipment.
- (f) Exit signs and an evacuation plan shall be posted and clearly visible. The evacuation plan shall detail evacuation routes for patients, staff, and visitors in case of fire or other emergency.
- (g) No smoking shall be permitted in patient care or treatment areas.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

### **10A NCAC 14F .2102 GRADED EXERCISE TESTING LABORATORY**

If the program performs graded exercise testing, the following facilities and equipment shall be available:

- (1) space for physical examination which allows for visual privacy;
- (2) adequate space and temperature and humidity controls for exercise as described under Rule .2101 of this Subchapter;
- (3) 12-lead ECG equipment for recording the ECG during exercise testing;
- (4) oscilloscope for ECG monitoring or continuous recording;
- (5) treadmill, bicycle ergometer, or arm crank ergometer;
- (6) blood pressure cuff and stethoscope;
- (7) emergency procedures, equipment, and supplies as described in Section .1900 of this Subchapter; and
- (8) access to spirometer for pulmonary function testing.

*History Note:* Authority G.S. 131E-169;  
Eff. July 1, 2000.

### **10A NCAC 14F .2103 EXERCISE THERAPY**

The following equipment shall be available and operable for the provision of exercise assessment and therapy:

- (1) ECG and oscilloscope;

- (2) blood pressure cuff and stethoscope;
- (3) large clock with sweep second hand;
- (4) blood glucose testing equipment; and
- (5) equipment for the performance of anthropometric measurements such as skinfold caliper, stadiometer, tape measure, and physician's scale.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .2104 NUTRITION SERVICES**

If provided on site, the following facilities and equipment shall be available for the provision of nutrition services:

- (1) space that allows for confidential interviewing and counseling;
- (2) nutrition guidelines and means of nutrient analysis; and
- (3) educational materials, as deemed appropriate by the program's dietitian/nutritionist, for patient distribution and use during nutrition therapy counseling.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .2105 MENTAL HEALTH SERVICES**

If provided on site, space shall be available for the provision of the mental health services to allow for confidential interviewing and counseling.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*

#### **10A NCAC 14F .2106 VOCATIONAL REHABILITATION SERVICES**

If provided on site, space shall be available for the provision of vocational rehabilitation services to allow for confidential interviewing and counseling.

*History Note: Authority G.S. 131E-169;  
Eff. July 1, 2000.*