DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

MEMORANDUM

DATE: December 15, 2017

TO: Interested Parties

FROM: Nadine Pfeiffer, Rule Review Manager

RE: Proposed Readoption/Amendment of Certification of Cardiac Rehabilitation Programs Rules - 10A NCAC 14F

GS 150B-21.2 requires a rule-making body to notify certain individuals of its intent to adopt a rule. It also requires notification of the date, time and location of the public hearing on the rule and any fiscal analysis that has been prepared in connection with the proposed rule. As a result of the periodic review of the Subchapter 10A NCAC 14F rules, six rules were determined as "Necessary With Substantive Public Interest" therefore must be readopted. One rule is being amended to update information in the rule.

The North Carolina Department of Health and Human Services/Director, DHSR has submitted form OAH 0300 to the Codifier of Rules, Office of Administrative Hearings, indicating its intent for the following rules:

10A NCAC 14F .1203	Certificate Renewal	(Readopt with substantive change)
10A NCAC 14F .1301	Staff Requirements and Responsibilities	(Readopt with substantive change)
10A NCAC 14F .1401	Patient Rights	(Amend)
10A NCAC 14F .1802	Exercise Therapy	(Readopt with substantive change)
10A NCAC 14F .1901	Emergency Plan	(Readopt without substantive change)
10A NCAC 14F .1903	Emergency Drills	(Readopt with substantive change)
10A NCAC 14F .2101	Physical Environment and Equipment	(Readopt with substantive change)

In accordance with G.S. 150B-21.3A(d)(2), a fiscal analysis was prepared for rules with substantive change. Approval of the fiscal analysis for these rules was obtained from the Office of State Budget and Management (OSBM) on October 11, 2017 in accordance with G.S. 150B-21.4. The revised fiscal analysis with no changes to fiscal impact was submitted to OSBM on November 21, 2017.

OFFICE OF THE DIRECTOR
WWW.NCDHHS.GOV
TEL 919-855-3750 • FAX 919-733-2757
LOCATION: 809 RUGGLES DRIVE • EDGERTON BUILDING • RALEIGH, NC 27603
MAILING ADDRESS: 2701 MAIL SERVICE CENTER • RALEIGH, NC 27699-2701
AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

The proposed rule text is attached to this memo. The rules were published in today's December 15, 2017 edition of the N.C. Register which can be found at the Office of Administrative Hearings web site at http://www.ncoah.com/rules/register.

A public hearing is scheduled for January 2, 2018 at 11:00 a.m. in Room 104, Brown Building, 801 Biggs Drive, Raleigh, NC 27603. The building is located in the Dorothea Dix Park. The Director, DHSR is accepting public comments on these rules and fiscal analysis from December 15, 2017 – February 13, 2018. Comments will also be accepted in person at the public hearing. The proposed effective date of these rules is June 1, 2018.

A copy of the proposed rules, fiscal analysis, and instructions for submitting comment can be found at the Division of Health Service Regulation web site at www.2ncdhhs.gov/dhsr/ruleactions.html.

Should you have questions related to this memorandum or the proposed rule and fiscal note, please feel free to contact the Acute and Home Care Licensure & Certification Section at (919) 855-4620.

Enclosures

cc: Mark Payne, Director, Health Service Regulation
Emery Milliken, Deputy Director, DHSR
Joel Johnson, Assistant General Counsel, DHHS
Azzie Conley, Chief, Acute and Home Care Licensure & Certification Section
Clarence Ervin, Assistant Chief, Acute and Home Care Licensure & Certification Section

10A NCAC 14F .1203 is proposed for readoption with substantive changes as follows:

10A NCAC 14F .1203 CERTIFICATE RENEWAL

(a) A certificate issued pursuant to ~~the Article~~ G.S. 131E-167 and this Subchapter shall expire ~~two years~~ one year after the effective date of the certificate, but ~~can~~ may 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.~~ in accordance with Rule .1202 of this Subchapter.

(b) Determination of compliance with the provisions of ~~the Article~~ G.S. 131E-167 and this Subchapter for purposes of certificate renewal ~~may, at the discretion of the Department,~~ may be based upon an inspection or upon review of requested information submitted by a program to the ~~Department.~~ Department in accordance with Rule .1205 of this Subchapter.

History Note: *Authority G.S. 131E-167; 131E-169;*
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. June 1, 2018.

10A NCAC 14F .1301 is proposed for readoption with substantive changes as follows:

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,~~ employ ~~full-time or part-time,~~ (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:~~ within their scope of practice as determined by their respective occupational licensing board:

(1) Program Director - supervises program staff and directs all facets of the program.

(2) Medical ~~Director B~~ Director - physician who provides medical assessments and is responsible for supervising all clinical aspects of the program and for assuring the ~~adequacy~~ availability of emergency ~~procedures and~~ procedures, equipment, testing equipment, and personnel.

(3) Nurse - provides nursing assessments and services.

(4) Exercise ~~Specialist~~ Specialist - provides an exercise assessment, ~~in consultation with the medical director,~~ plans and evaluates exercise ~~therapies.~~ therapies in consultation with the medical director.

(5) Mental Health Professional - ~~provides directly~~ directly provides or assists program staff in completion of the mental health screening and referral, if ~~indicated, for~~ further mental health ~~services.~~ services are necessary.

(6) Dietitian or Nutritionist - ~~provides directly~~ directly provides or assists program staff in completion of the nutrition assessment and referral, if ~~indicated, for~~ further nutrition ~~services.~~ services are necessary.

(7) Supervising Physician, Physician Assistant, or Nurse Practitioner - medical person who is on-site during the hours of 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.~~ those patients.

History Note: *Authority G.S. 131E-169;*
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. June 1, 2018.

10A NCAC 14F .1401 is proposed for amendment as follows:

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 at least five years showing that ~~all~~ patients have been informed of their rights and responsibilities.

(b) Each patient's rights and responsibilities shall ~~include, at a minimum,~~ include the right to:

(1) be informed of and participate in developing the patient's plan of care;

(2) ~~voice grievances~~ file a grievance about the care provided, and not be subjected to discrimination or reprisal for doing so;

(3) ~~confidentiality of the patient's records;~~ have his or her records kept confidential;

(4) be informed with notice 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~~ 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.~~ telephone number for the Complaint Intake of the Division: 1-800-624-3004 and 919-855-4500 (within North Carolina).

(d) The program shall ~~investigate, within seven days,~~ investigate complaints within seven days of receipt by ~~made to~~ the program ~~by~~ from the patient, the patient's family, or ~~significant other,~~ domestic partner, and ~~must~~ shall document both the existence of the ~~complaint~~ complaint, ~~and~~ the resolution of the ~~complaint.~~ complaint, and retain documents in the records for five years from date of resolution.

History Note: *Authority G.S. 131E-169;*
Eff. July 1, 2000;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 6, ~~2016.~~ 2016;
Amended Eff. June 1, 2018.

10A NCAC 14F .1802 is proposed for readoption with substantive changes as follows:

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~~ The patient's first exercise session ~~must~~ shall include ~~objective~~ an objective initial 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:~~ The patients exercise therapy shall be developed based on needs identified by the initial assessment. Guidelines regarding exercise testing and prescription for exercise therapy are identified in the American College of Sports Medicine 10th edition, incorporated herein by reference including subsequent changes and editions. Copies of the American College of Sports Medicine guidelines are available from http://www.acsmstore.org/ProductDetails.asp?ProductCode=9781496339072 at a cost of forty seven dollars and ninety nine cents ($47.99). The following Chapters of these guidelines apply to the cardiac rehabilitation program:

(1) Chapters 3 through 7 that describe the "Pre-exercise Evaluation," "Health-Related Physical Fitness Testing and Interpretation," "Clinical Exercise Testing and Interpretation," "General Principles of Exercise Prescription," and "Exercise Prescription for Healthy Populations with Special Consiterations;" and

(2) Chapter 9 that describes "Exercise Prescription for Patients with Cardiac, Peripheral, Cerebrovascular and Pulmonary Disease."

~~(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~~ 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.~~ documented by the exercise specialist in accordance with hospital or Cardiac Rehabilitation Program policy.

(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)~~ patient's treatment plan. Feedback concerning changes in the ~~exercise therapy~~ patient's treatment plan 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~~ per hospital or Cardiac Rehabilitation Program policy 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.~~ 2000;
Readopted Eff. June 1, 2018.

10A NCAC 14F .1901 is proposed for readoption without substantive change as follows:

10A NCAC 14F .1901 EMERGENCY PLAN

~~A~~ The facility shall establish and maintain a written plan signed and approved ~~and signed~~ by the medical director ~~shall be established~~ to ~~handle any~~ address emergencies occurring on site while cardiac rehabilitation services are being provided. All areas of the premises ~~pertinent to~~ necessary for 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.~~ 2000;
Readopted Eff. June 1, 2018.

10A NCAC 14F .1903 is proposed for readoption with substantive changes as follows:

10A NCAC 14F .1903 EMERGENCY DRILLS

(a) ~~At least six~~ Quarterly patient emergency drills shall be conducted by the Cardiac Rehabilitation Program each year when patients are on-site and shall be ~~documented.~~ documented by the program director or designee.

(b) Drill sites shall be rotated through all locations used by patients while participating in program activities.

(c) The drill documentation and ~~effectiveness~~ results of emergency drills shall be ~~reviewed and signed~~ reviewed, signed, and dated by the medical director or supervising ~~physician.~~ physician in accordance with hospital or Cardiac Rehabilitation Program policy.

History Note: *Authority G.S. 131E-169;*
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. June 1, 2018.

10A NCAC 14F .2101 is proposed for readoption with substantive changes as follows:

10A NCAC 14F .2101 PHYSICAL ENVIRONMENT AND EQUIPMENT

(a) The program shall provide a clean and safe environment. For the purposes of this Rule, "clean and safe" means visibly free of soil, and other debris, and maintained in an orderly condition where there are no obstacles that would present risks to the patient.

(b) Equipment and furnishings shall be cleaned ~~not less than weekly.~~ between patients in accordance with manufacturer's instructions and the cardiac rehabilitation program's procedures for infection control and universal precautions.

(c) All areas of the facility shall be ~~orderly and~~ free of ~~debris~~ 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~~ shall allow easy access of personnel and equipment.

(f) Exit signs and an evacuation plan shall be posted and clearly ~~visible.~~ visible to program patients, staff, and visitors. 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.~~ in the facility.

History Note: *Authority G.S. 131E-169;*
Eff. July 1, ~~2000.~~ 2000;
Readopted Eff. June 1, 2018.