AGENCY: DHHS/ Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .1203

#### DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

# <u>PLEASE NOTE:</u> This request may extend to several pages. Please be sure you have reached the end of the document.

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (b), line 9, are you saying that the determination of compliance shall be based upon either the inspection or upon information submitted pursuant to Rule .1205? If not, then what do you mean by "may" on line 9?

10A NCAC 14F .1203 is readopted as published in 32:12 NCR 1185-1188 as follows:

- 3 10A NCAC 14F .1203 CERTIFICATE RENEWAL
- 4 (a) A certificate issued pursuant to the Article <u>G.S. 131E-167</u> and this Subchapter shall expire two years <u>one year</u>
- 5 after the effective date <u>of the certificate</u>, but <del>can</del> <u>may</u> be renewed upon the <del>successful</del> re-evaluation of the program.
- 6 To initiate the renewal process, an application for certification shall be filed with the Department by the owner of the
- 7 program. in accordance with Rule .1202 of this Subchapter.
- 8 (b) Determination of compliance with the provisions of the Article <u>G.S. 131E-167</u> and this Subchapter for purposes
- 9 of certificate renewal may, at the discretion of the Department, may be based upon an inspection or upon review of
- 10 requested information submitted by a program to the Department. Department in accordance with Rule .1205 of this
- 11 Subchapter.
- 12
- 13 History Note: Authority G.S. 131E-167; 131E-169;
- 14 Eff. July 1, 2000. 2000:
- 15 <u>Readopted Eff. June 1, 2018.</u>

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .1301

#### DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 6, just so I'm clear – I take it "DVRS" is the term as defined in Rule .1101 of this Subchapter?

In (b), line 10, should this sate "Individuals may perform multiple team functions <u>listed in this</u> <u>Rule.</u>"? It seems that you may be missing some language here.

In (b)(4), line 17, should this be "provides an exercise assessment and plans and evaluates..."?

In (b)(5), line 22, and (b)(6), line 25, who decides if the services are necessary? The individual that will provide the services?

10A NCAC 14F .1301 is readopted with changes as published in 32:12 NCR 1185-1188 as follows:

3 10A NCAC 14F .1301 STAFF REQUIREMENTS AND RESPONSIBILITIES

4 (a) Each program shall be conducted utilizing an interdisciplinary team composed of a program director, medical 5 director, nurse, exercise specialist, program staff, mental health professional, dietician or nutritionist, supervising 6 physician, physician assistant or nurse practitioner, and a DVRS or other vocational rehabilitation counselor. The 7 program may employ, employ full time or part time, (full-time or part-time), or contract for the services of team 8 members. Program staff shall be available to patients as needed to perform initial assessments and to implement each 9 patient's cardiac rehabilitation care plan. 10 (b) Individuals may perform multiple team functions, if qualified for each function, as stated in this Rule: within their 11 scope of practice as determined by their respective occupational licensing board:

- 12 (1) Program Director supervises program staff and directs all facets of the program.
- 13 (2) Medical Director B Director physician who provides medical assessments and is responsible for
   14 supervising all clinical aspects of the program and for assuring the adequacy availability of
   15 emergency procedures and procedures, equipment, testing equipment, and personnel.
- 16 (3) Nurse provides nursing assessments and services.
- 17 (4) Exercise Specialist [Specialist ] Program Staff provides an exercise assessment, in consultation
   18 with the medical director, plans and evaluates exercise therapies. therapies in consultation with the
   19 medical director.
- 20 (5) Mental Health Professional provides directly directly provides or assists program staff the
   21 interdisciplinary team in completion of the mental health screening and referral, if indicated, for
   22 further mental health services. services are necessary.
- 23 (6) Dietitian or Nutritionist provides directly <u>directly provides</u> or assists program staff the
   24 <u>interdisciplinary team</u> in completion of the nutrition assessment and referral, if <del>indicated, for</del> further
   25 nutrition services. services are necessary.
- 26 (7) Supervising Physician, Physician Assistant, or Nurse Practitioner medical person who is on-site
   27 during the <u>hours of</u> 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.

33	History Note:	Authority G.S. 131E-169;
34		Eff. July 1, <del>2000.</del> <u>2000;</u>
35		<u>Readopted Eff. June 1, 2018</u>

32

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .1401

#### DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (d), line 22, you state "both" but then list three things. Consider either deleting "both" or keeping the language as it was "both the existence of the complaint and the resolution of the complaint, and retain..."

10A NCAC 14F .1401 is amended as published in 32:12 NCR 1185-1188 as follows:

#### 3 10A NCAC 14F .1401 PATIENT RIGHTS

4 (a) Prior to or at the time of admission, the program shall provide each patient with a written notice of the patient's 5 rights and responsibilities. The program shall maintain documentation at least five years showing that all patients 6 have been informed of their rights and responsibilities. 7 (b) Each patient's rights and responsibilities shall include, at a minimum, include the right to: 8 (1)be informed of and participate in developing the patient's plan of care; 9 (2)voice grievances file a grievance about the care provided, and not be subjected to discrimination or 10 reprisal for doing so; 11 (3) confidentiality of the patient's records; have his or her records kept confidential; 12 (4)be informed with notice of the patient's liability for payment for services; 13 (5) be informed of the process for acceptance and continuation of service and eligibility determination; 14 (6)accept or refuse services; and 15 (7)be advised of the program's procedures for discharge. 16 (c) The program shall provide all patients with a telephone number for information, questions questions, or complaints 17 about services provided by the program. The program shall also provide the Division Complaints Hotline number or 18 the Department of Health and Human Services Careline number or both. telephone number for the Complaint Intake 19 of the Division: 1-800-624-3004 and 919-855-4500 (within North Carolina). 20 (d) The program shall investigate, within seven days, investigate complaints within seven days of receipt by made to 21 the program by from the patient, the patient's family, or significant other, domestic partner, and must shall document 22 both the existence of the complaint complaint, and the resolution of the complaint. complaint, and retain documents 23 in the records for five years from date of resolution. 24 25 History Note: Authority G.S. 131E-169; 26 Eff. July 1, 2000; 27 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. December 28 6, <del>2016.</del> 2016; 29 Amended Eff. June 1, 2018.

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .1802

## DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (c), line 10, please state "patient's"

On line 12, consider replacing "changes" with "amendments"

On line 15, why is the term "Chapters" capitalized?

In (c)(1), line 16, and (c)(2), line 20, do you really mean "describes"? Are these the names of the Chapter? If so, why not just state "Chapters 3 through 7, "Pre-exercise Evaluation..."? Or are you concerned that the names of the chapters will change in subsequent editions, such that you need to retain the subject matter discussed for ease of your regulated public?

In (d), line 36, please state "monitoring, continuous or intermittent, shall be..."

In (e), line 3, Page 2, and (g), lines 12-13, why is "Cardiac Rehabilitation Program" capitalized?

And for both uses, is the policy an internal policy for the individual program?

In (f), line 4, why did you strike "patient's"? Will those who use the Rule know that a "personal physician" is for the patient?

In (f), line 7, so that I'm clear – if there is feedback from the consultation with the medical director of the personal physician, then that is discussed with the patient and documented in the patient's record?

In (g), line 13, what is a "carbohydrate source"? Should you have retained "food" here?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder Commission Counsel Date submitted to agency: April 24, 2018

10A NCAC 14F .1802 is readopted with changes as published in 32:12 NCR 1185-1188 as follows:

3 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.

6 (b) If any patient has not had a graded exercise test prior to the first exercise session, the The patient's first exercise

7 session must shall include objective an objective initial assessment of hemodynamic data, ECG, and symptom 8 response data.

9 (c) Unless contraindicated by medical and laboratory assessments or the cardiac rehabilitation care plan, each patient's

10 exercise therapy shall include: The patients exercise therapy shall be developed based on needs identified by the initial

11 assessment. Guidelines regarding exercise testing and prescription for exercise therapy are identified in the American

12 College of Sports Medicine 10<sup>th</sup> edition, incorporated herein by reference including subsequent changes and editions.

13 Copies of the American College of Sports Medicine guidelines are available from http://www.acsmstore.org/Product

14 Details.asp?ProductCode=9781496339072 at a cost of forty seven dollars and ninety nine cents (\$47.99). The

15 <u>following Chapters of these guidelines apply to the cardiac rehabilitation program:</u>

 16
 (1)
 Chapters 3 through 7 that describe the "Pre-exercise Evaluation," "Health-Related Physical Fitness

 17
 Testing and Interpretation," "Clinical Exercise Testing and Interpretation," "General Principles of

 18
 Exercise Prescription," and "Exercise Prescription for Healthy Populations with Special

 19
 Consiterations;" and

20 (2) Chapter 9 that describes "Exercise Prescription for Patients with Cardiac, Peripheral,
 21 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;
- 24 (2) intensity:

25 (A) up to 85 percent of symptom limited heart rate reserve;

- 26 (B) up to 80 percent of measured maximal oxygen consumption;
- 27 (C) rating of perceived exertion (RPE) of 11 to 13 if a graded exercise test is not performed; or
- 28 (D) for myocardial infarction patients: heart rate not to exceed 20 beats per minute above 29 standing resting heart rate if a graded exercise test is not performed; and for post coronary 30 artery by pass graft patients: heart rate not to exceed 30 beats per minute above standing 31 resting heart rate if a graded exercise test is not performed;
- 32 (3) duration: up to 60 minutes, as tolerated, including a minimum of five minutes each for warm up and
   33 cool down; and
- 34 (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 <u>continuous</u> <u>continuous</u>, or intermittent, shall be based on medical acuity and risk

37 stratification.

1 (e) At two week intervals, the patient's adherence to the cardiac rehabilitation care plan and progress toward goals 2 shall be monitored by an examination of exercise therapy records and documented. documented by the exercise 3 specialist in accordance with hospital or Cardiac Rehabilitation Program policy. 4 (f) The exercise specialist program staff shall be responsible for consultation with the medical director or the patient's 5 personal physician concerning changes in the exercise therapy, results of graded exercise tests, as needed or anticipated 6 (e.g. regular follow up intervals, graded exercise test conducted, or medication changes) patient's treatment plan. 7 Feedback concerning changes in the exercise therapy patient's treatment plan shall be discussed with the patient and 8 documented. 9 (g) Diabetic patients who are taking insulin or oral hypoglycemic agents for control of diabetes shall have blood 10 sugars monitored for at least the first week of cardiac therapy sessions in order to establish the patient's level of control 11 and subsequent response to exercise. Cardiac rehabilitation staff shall record blood sugar measurements pre- and post-12 exercise. Patients whose blood sugar values are considered abnormal for the particular patient per hospital or Cardiac 13 Rehabilitation Program policy shall be monitored. A carbohydrate food source or serving shall be available. Snacks 14 shall be available in case of a hypoglycemic response. 15 16 History Note: Authority G.S. 131E-169; 17 Eff. July 1, 2000. 2000;

18 <u>Readopted Eff. June 1, 2018.</u>

10A NCAC 14F .1901 is readopted as published in 32:12 NCR 1185-1188 as follows:

#### 3 10A NCAC 14F .1901 EMERGENCY PLAN

4 A The facility shall establish and maintain a written plan signed and approved and signed by the medical director shall

5 be established to handle any <u>address</u> emergencies occurring on site while cardiac rehabilitation services are being

6 provided. All areas of the premises pertinent to necessary for program operation shall be included. The plan shall

- 7 address the assignment of personnel and availability of equipment required in an emergency.
- 8

9 History Note: Authority G.S. 131E-169;

10 *Eff. July 1, <del>2000.</del> <u>2000;</u>* 

11 <u>Readopted Eff. June 1, 2018.</u>

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .1903

## DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (a), line 4, and (c), lines 8-9, why is the term "Cardiac Rehabilitation Program" capitalized?

On line 5, you hyphenate "on-site" but you do not in a similar usage in Rule .1901, line 5. Please either change this usage or the one in Rule .1901.

On line 9, is this the policy of the individual facility?

10A NCAC 14F .1903 is readopted as published in 32:12 NCR 1185-1188 as follows:

#### 3 10A NCAC 14F .1903 EMERGENCY DRILLS

4 (a) At least six Quarterly patient emergency drills shall be conducted by the Cardiac Rehabilitation Program each

- 5 year <u>when patients are on-site</u> and shall be <del>documented.</del> <u>documented by the program director or designee.</u>
- 6 (b) Drill sites shall be rotated through all locations used by patients while participating in program activities.
- 7 (c) The drill documentation and effectiveness results of emergency drills shall be reviewed and signed reviewed,
- 8 signed, and dated by the medical director or supervising physician. physician in accordance with hospital or Cardiac
- 9 <u>Rehabilitation Program policy.</u>
- 10
- 11 History Note: Authority G.S. 131E-169;
- 12 *Eff. July 1, <del>2000.</del> <u>2000:</u>*
- 13 <u>Readopted Eff. June 1, 2018.</u>

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14F .2101

## DEADLINE FOR RECEIPT: Tuesday, May 8, 2018

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In (b), line 8, I note that the term "cardiac rehabilitation program" is not capitalized.

On lines 8-9, I take it "universal precautions" is a term known to your regulated public?

In (c), line 10, isn't "free of debris" duplicative of the language on line 5? Do you need it both places?

In (d), line 11, I take it that the program must establish the preventative maintenance program?

In (e), line 13, I take it "easy access" is a known term to your regulated public?

- 1 2
- 10A NCAC 14F .2101 is readopted as published in 32:12 NCR 1185-1188 as follows:
- 3 10A NCAC 14F .2101 PHYSICAL ENVIRONMENT AND EQUIPMENT
  - 4 (a) The program shall provide a clean and safe environment. For the purposes of this Rule, "clean and safe" means
  - 5 visibly free of soil, and other debris, and maintained in an orderly condition where there are no obstacles that would
  - 6 present risks to the patient.
  - 7 (b) Equipment and furnishings shall be cleaned not less than weekly. between patients in accordance with
  - 8 manufacturer's instructions and the cardiac rehabilitation program's procedures for infection control and universal
  - 9 precautions.
  - 10 (c) All areas of the facility shall be orderly and free of debris debris, and with clear traffic areas.
  - 11 (d) A written and documented preventative maintenance program shall be established to ensure that all equipment is
  - 12 calibrated and maintained in safe and proper working order in accordance with manufacturers' recommendations.
  - 13 (e) There shall be emergency access to all areas a patient may enter, and floor space must shall allow easy access of
  - 14 personnel and equipment.
  - 15 (f) Exit signs and an evacuation plan shall be posted and clearly visible. visible to program patients, staff, and visitors.
  - 16 The evacuation plan shall detail evacuation routes for patients, staff, and visitors in case of fire or other emergency.
  - 17 (g) No smoking shall be permitted in patient care or treatment areas. in the facility.
  - 18
  - 19 History Note: Authority G.S. 131E-169;
  - 20 *Eff. July 1, <del>2000.</del> <u>2000;</u>*
  - 21 <u>Readopted Eff. June 1, 2018.</u>