DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION

ROY COOPER
GOVERNOR

MANDY COHEN, MD, MPH
SECRETARY

MARK PAYNE
DIRECTOR

MINUTES OF PUBLIC HEARING
JANUARY 2, 2018
11:00 A.M.

Division Staff Present:
Nadine Pfeiffer, Rule-review Coordinator
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section

Others Present:
Connie Paladenech, N.C. Cardiopulmonary Rehabilitation Association/Wake Forest Baptist Hospital
Mary Ann Compton, N.C. Cardiopulmonary Rehabilitation Association/UNC Hospitals

1. Purpose of Hearing

The purpose of this public hearing was to solicit verbal and/or written comments from the public on the proposed Certification of Cardiac Rehabilitation Programs rule readoptions and rule amendment, specifically: 10A NCAC 14F .1203, .1301, .1401, .1802, .1901, .1903, and .2101, as published in the NC Register, Volume 32, Issue 12, issued on December 15, 2017, as well as the fiscal note for these rules.

2. Hearing Summary

The Public Hearing was opened by Nadine Pfeiffer at 11:00 a.m. Attending were representatives from the provider community. Two oral comments were recorded for the rules. In addition, one written comment was given to the Agency. A summary of these comments is as follows:

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AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

a) Connie Paladenech spoke on behalf of the N.C. Cardiopulmonary Rehabilitation Association and her employer, Wake Forest Baptist Hospital. (written comments attached)

Ms. Paladenech stated the association was supportive of rule 10A NCAC 14F .1203 Certificate Renewal; however, it suggests adding a clause to Paragraph (b) saying "or current program certification by the American Association of Cardiovascular and Pulmonary Rehabilitation." The rationale being the AACPR is the accrediting body for both cardiac and pulmonary rehab programs that has a stringent set of guidelines and credentialing process. It is hoped this certification could be considered in lieu of the State's.

Ms. Paladenech stated that for rule 10A NCAC 14F .1301 Staff Requirements and Responsiblities, the term "program director" is used in the proposed rule; however, the term that is used across the state, and the management trend now, is the term "manager." She stated the association suggests changing the term in rule to say "program director/manager" and also add a phrase about the medical director that says "responsible for directing all clinical aspects of the program." Ms. Paladenech stated that on a side note in the same section, CMS requires that Cardiac Rehabilitation programs be supervised by an MD or DO. Nurse practitioners and physician assistants are not approved by CMS to supervise or order cardiac rehabilitation services. Therefore, Ms. Paladenech questioned whether the reference to physician assistant and nurse practitioner should be deleted in the rule. Ms. Paladenech stated that where the rule defines the "Medical Director" in Subparagraph (b)(2), the association suggests adding the clause "including the duration and type of ECG and other monitoring." The rationale being the change in the use of ECG monitoring in the US from what it was and to allow programs more latitude to adjust the frequency of monitoring based on the patient's need. Ms. Paladenench stated for the definition of "supervising physician" in Subparagraph (b)(7), the association questioned whether the terms "physician assistant" and "nurse practitioner" should be struck in the rule. The rationale being as previously stated that CMS does not recognize nurse practitioners or physician assistants as being able to order or supervise cardiac rehab programs. Ms. Paladenench stated for the definition of "DVRS or other Vocational Rehabilitation Counselor" in Subparagraph (b)(8), there has been a change in how the DVRS counselors function. In previous years, patients were given a cardiac diagnosis and there was a huge need for vocational rehabilitation counseling. It is very rare now with the current treatment for cardiac rehabilitation. Most patients are able to resume their previous occupation. Therefore Ms. Paladenech questioned whether that subparagraph needed to deleted.

Ms. Paladenech stated that for rule 10A NCAC 14F .1802 Exercise Therapy, the association suggests in Paragraph (a), adding the clause "and type and duration of ECG and other monitoring." Ms. Paladenech stated the association suggests in Paragraph (b), adding the clause "including resting, exercise and recovery, BP, heart rate response, ECG and signs and symptoms of exercise intolerance. This data shall be used to establish the initial individualized exercise prescription consistent with the most current American College of Sports Medicine Guidelines regarding Exercise Testing and Prescription." She stated that despite the excellent description that has been added to the proposed rule, the rationale for the suggested change is that the current regulation is 17 years old and revisions would occur at two year intervals. A new edition of the guidelines is due in the fall of 2018. The content will be the same, but the page numbers and cost of the

publication will be different than in the proposed rule, so it is suggested to use more of a general reference to require less revision. Also for Paragraph (b), Ms. Paladenech stated that the association suggested adding this statement to the end, "These shall be monitored during each exercise session as appropriate for the individual's medical acuity and risk stratification based on the most recent AACVPR and ACSM Guidelines and as deemed appropriate by the medical director in consultation with program staff." Ms. Paladenech stated that in Paragraph (e), the association suggests changing the "two week intervals" requirement for reviewing the individualized treatment plan to "30 day intervals" to be consistent with what CMS requires. She stated the association also suggests to refer to the "ITP", or the "individualized treatment plan" in the rule as well as adding "cardiac rehabilitation staff." Ms. Paladenech stated that in Paragraph (f), the rule referred to the exercise specialist. She stated that the association felt it was important for the rule to say "multidisciplinary cardiac rehabilitation staff" because a multidisciplinary approach is used for the patient's treatment plan, that includes the exercise plan. She also stated the association suggests changing the rule to say "individualized treatment plan (ITP)." Ms. Paladenech stated that in Paragraph (g), the association suggests adding that blood sugars should be monitored "in accordance with institutional policy" and striking "for at least the first week of cardiac therapy sessions and staff shall record blood sugar measurements pre and post exercise." She stated the association suggests to add "Patients shall be trained to identify signs and symptoms of hypo-and hyperglycemia and self-management of their condition." The rationale being the blood sugar is important, but because of the variation, it needs to be individualized. Some patients understand, but others require more intensive monitoring.

Ms. Paladenech stated that for rule 10A NCAC 14F .2101 Physical Environment and Equipment, the association suggests adding the statement to the end of Paragraph (c), "as defined by the American College of Sports Medicine." In Paragraph (f), Ms. Paladenech questioned whether the State still requires the posting of an evacuation plan and if it has changed, then the wording would need to be changed to reflect the change.

Ms. Conley addressed Ms. Paladenech's question regarding the posting of the evacuation plan by stating that not all cardiac rehabilitation programs are located in hospital settings, therefore changes in rules must be mindful of where the programs are located. The expectation is the evacuation plan be posted. CMS has implemented new emergency preparedness guidelines that all providers need to operate under.

b) Mary Ann Compton spoke on behalf of N.C. Cardiopulmonary Rehabilitation Association and her employer, UNC Hospitals.

Ms. Compton reiterated support for the comments addressed by Ms. Paladenech and their organization. She expressed concern over the comment about striking the requirement for the physician assistant or nurse practitioner. Ms. Compton stated that the association is hoping to ask CMS to change, so if changes are made to this rule and CMS adds it back in to their rules, she questioned what would that mean. There is great value to have the nurse practitioner and physician assistants involved. The bill Congress approved providing coverage for cardiac rehab specifically stated that supervision must specifically be by an MD or a DO and that restricts access to care for patients.

3. Adjournment

These comments will be taken into consideration by the Agency. The hearing was adjourned at 11:24 a.m.

Respectfully Submitted,

Nadine Pfeiffer, Rule-making Coordinator
January 2, 2018

Attachments

Public Hearing Attendance
Certification of Cardiac Rehabilitation Programs Rules
10A NCAC 14F ,1203, .1301, .1401, .1802, .1901, .1903, .2101
January 2, 2018   11:00 a.m.

Please print information below:

Name	**Representing**	**Speaking Yes(Y)No(N)**
Connie Paladenech	North Carolina Cardiopulmonary Rehabilitation Association/Wake Forest Baptist Health	Y
Mary Ann Compton	North Carolina Cardiopulmonary Rehabilitation Association/ UNC Hospitals	Y

Date: December 28, 2017

To: Director, DHSR

From: Connie Paladenech, RRT, RCP, FAARC, Legislative Liaison
North Carolina Cardiopulmonary Rehabilitation Association Response to
Department of Health and Human Services Division of Health Service Regulation

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

Please see North Carolina Cardiac and Pulmonary Rehabilitation Association comments in red italics below.
Thank you for the opportunity to provide comment on the Proposed Readoption / Amendment of Certification of Cardiac Rehabilitation Program Rules – 10A NCAC 14F.

10A NCAC 14F .1203 is proposed for readoption with substantive changes as follows: 1
2
10A NCAC 14F .1203 CERTIFICATE RENEWAL 3
(a) A certificate issued pursuant to the Article G.S. 131E-167 and this Subchapter shall expire two years one year 4 after the effective date of the certificate, but can may be renewed upon the successful re-evaluation of the program. 5 To initiate the renewal process, an application for certification shall be filed with the Department by the owner of the 6 program. in accordance with Rule .1202 of this Subchapter. 7
(b) Determination of compliance with the provisions of the Article G.S. 131E-167 and this Subchapter for purposes 8 of certificate renewal may, at the discretion of the Department, may be based upon an inspection or upon review of 9 requested information submitted by a program to the Department. Department in accordance with Rule .1205 of this 10 Subchapter. 11 *or current program certification by the American Association of Cardiovascular and Pulmonary Rehabilitation.*
12
History Note: Authority G.S. 131E-167; 131E-169; 13
Eff. July 1, 2000. 2000; 14
Readopted Eff. June 1, 2018. 15

10A NCAC 14F .1301 is proposed for readoption with substantive changes as follows: 1
2
10A NCAC 14F .1301 STAFF REQUIREMENTS AND RESPONSIBILITIES 3
(a) Each program shall be conducted utilizing an interdisciplinary team composed of a program director*/manager*, medical 4 director, *responsible for directing all clinical aspects of the program,* nurse, exercise specialist, mental health professional, dietician or nutritionist, supervising physician, ~~5 physician assistant or nurse practitioner~~ *(CMS requires that Cardiac Rehabilitation programs be supervised by an MD or DO. Norse practitioners and physician assistants are not approved by CMS to supervise or order cardiac rehabilitation services.)*, ~~and a DVRS or other vocational rehabilitation counselor.~~ (NCCRA recommends deletion of this statement due to the fact that DVRS counselors are no longer assigned to cardiac rehabilitation programs and advances in medical management of cardiovascular disease make it possible for many patients previously considered disabled to now return to their previous functional level and employment.) The program may 6 employ, employ full-time or part-time, (full-time or part-time), or contract for the services of team members. Program 7 staff shall be available to patients as needed to perform initial assessments and to implement each patient's cardiac 8 rehabilitation care plan. 9
(b) Individuals may perform multiple team functions, if qualified for each function, as stated in this Rule: within their 10 scope of practice as determined by their respective occupational licensing board: 11

(1) Program Director - supervises program staff and directs all facets of the program. 12
(2) Medical ~~Director B~~ Director - physician who provides medical assessments and is responsible for 13 supervising all clinical aspects of the program and for assuring the ~~adequacy~~ availability of 14 emergency procedures and procedures, equipment, testing equipment, and personnel *including the duration and type of ECG and other monitoring* . 15
(3) Nurse - provides nursing assessments and services. 16
(4) Exercise ~~Specialist~~ Specialist/Exercise Physiologist - provides an exercise assessment, in consultation with the medical 17 director, plans and evaluates exercise therapies. therapies in consultation with the medical director. 18
(5) Mental Health Professional - provides directly directly provides or assists program staff in 19 completion of the mental health screening and referral, if indicated, for further mental health 20 services. services are necessary. 21
(6) Dietitian or Nutritionist - provides directly directly provides or assists program staff in completion 22 of the nutrition assessment and referral, if indicated, for further nutrition services. services are 23 necessary. 24
(7) Supervising Physician, ~~Physician Assistant, or Nurse Practitioner~~ *(CMS rules require MD or DO supervision of cardiac rehabilitation programs. Nurse practitioners and physician assistants cannot order or supervise cardiac rehabilitation services.)*- medical person who is on-site 25 during the hours of operation of programs that are not located within a hospital. 26
~~(8) DVRS or other Vocational Rehabilitation Counselor – screens patients who may be eligible for and 27 interested in vocational rehabilitation services, develops assessment and intervention strategies, and 28 provides other services as needed to meet the vocational goal(s) of patients who may be eligible for 29 and interested in services.~~ ~~those patients. 30~~ *VR counselors are no longer assigned to cardiac rehabilitation programs as they have been in the past.)*
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History Note: Authority G.S. 131E-169; 32
Eff. July 1, 2000. 2000; 33
Readopted Eff. June 1, 2018. 34

10A NCAC 14F .1802 is proposed for readoption with substantive changes as follows: 1
2
10A NCAC 14F .1802 EXERCISE THERAPY 3
(a) The medical director, in consultation with program staff, shall establish staff to patient ratios *and type and duration of ECG and other monitoring* for exercise therapy 4 sessions based on medical acuity, utilizing an acceptable risk stratification model. 5
(b) ~~If any patient has not had a graded exercise test prior to the first exercise session, the~~ The patient's first exercise 6 session ~~must~~ shall include ~~objective~~ an objective initial assessment of hemodynamic data, ECG, and symptom 7 response data *including resting, exercise and recovery BP, heart rate response, ECG and signs and symptoms of exercise intolerance. 8 This data shall be used to establish the initial individualized exercise prescription consistent with the most current American College of Sports Medicine Guidelines regarding Exercise Testing and Prescription.*
~~(c) Unless contraindicated by medical and laboratory assessments or the cardiac rehabilitation care plan, each patient's 9 exercise therapy shall include: The patients exercise therapy shall be developed based on needs identified by the initial 10 assessment. Guidelines regarding exercise testing and prescription for exercise therapy are identified in the American 11 College of Sports Medicine 10th edition, incorporated herein by reference including subsequent changes and editions. 12 Copies of the American College of Sports Medicine guidelines are available from http://www.acsmstore.org/Product 13 Details.asp?ProductCode=9781496339072 at a cost of forty seven dollars and ninety nine cents ($47.99). The 14 following Chapters of these guidelines apply to the cardiac rehabilitation program: 15~~
~~(1) Chapters 3 through 7 that describe the "Pre-exercise Evaluation," "Health-Related Physical Fitness 16 Testing and Interpretation," "Clinical Exercise Testing and Interpretation," "General Principles of 17 Exercise Prescription," and "Exercise Prescription for Healthy Populations with Special 18 Consiterations;" and 19~~
~~(2) Chapter 9 that describes "Exercise Prescription for Patients with Cardiac, Peripheral, 20 Cerebrovascular and Pulmonary Disease." 21~~
~~(1) mode of exercise therapy including, but not limited to: walk/jog, aquatic activity, cycle ergometry, 22 arm ergometry, resistance training, stair climbing, rowing, aerobics; 23~~
~~(2) intensity: 24~~
~~(A) up to 85 percent of symptom-limited heart rate reserve; 25~~

~~(B) up to 80 percent of measured maximal oxygen consumption; 26~~
~~(C) rating of perceived exertion (RPE) of 11 to 13 if a graded exercise test is not performed; or 27~~
~~(D) for myocardial infarction patients: heart rate not to exceed 20 beats per minute above 28 standing resting heart rate if a graded exercise test is not performed; and for post coronary 29 artery by-pass graft patients: heart rate not to exceed 30 beats per minute above standing 30 resting heart rate if a graded exercise test is not performed; 31~~
~~(3) duration: up to 60 minutes, as tolerated, including a minimum of five minutes each for warm-up and 32 cool-down; and 33~~
~~(4) frequency: minimum of three days per week. 34~~
~~(d) The patient shall be monitored through the use of electrocardiography during each exercise therapy session. The 35 frequency of the monitoring continuous continuous, or intermittent, shall be based on medical acuity and risk 36 stratification. 37 11/21/17~~ *The shall be monitored during each exercise session as appropriate for the individual's medical acuity and risk stratification based on the most recent AACVPR and ACSM Guidelines and as deemed appropriate by the medical director in consultation with program staff.*
2 of 2

(e) At *a minimum of 30 day intervals* ~~two week intervals~~, the patient's adherence to the *individualized treatment plan (ITP)* ~~cardiac rehabilitation care plan~~ and progress toward goals 1 shall be monitored by an examination of exercise therapy records and documented~~. documented~~ by the *cardiac rehabilitation staff* in accordance with hospital or Cardiac Rehabilitation Program policy. 3
(f) The *multidisciplinary cardiac rehabilitation staff* shall be responsible for consultation with the medical director or the patient's personal 4 physician concerning changes in the exercise therapy, results of graded exercise tests, as needed or anticipated (e.g. 5 regular follow-up intervals, graded exercise test conducted, or medication changes) patient's treatment plan. Feedback 6 concerning changes in the ~~*exercise therapy patient's*~~ *individualized* treatment plan *(ITP)* shall be discussed with the patient and 7 documented. 8
(g) Diabetic patients who are taking insulin or oral hypoglycemic agents for control of diabetes shall have blood 9 sugars monitored *in accordance with institutional policy* ~~for at least the first week of cardiac therapy sessions~~ in order to establish the patient's level of control 10 and subsequent response to exercise. ~~Cardiac rehabilitation staff shall record blood sugar measurements pre- and post-11 exercise.~~ Patients whose blood sugar values are considered abnormal for the particular patient per hospital or Cardiac 12 Rehabilitation Program policy shall be monitored. A carbohydrate food source or serving shall be available. Snacks 13 shall be available in case of a hypoglycemic response. 14 *Patients shall be trained to identify signs and symptoms of hypo- and hyperglycemia and self-management of their condition.*
15
History Note: Authority G.S. 131E-169; 16
Eff. July 1, 2000. 2000; 17
Readopted Eff. June 1, 2018. 18

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