Fiscal Impact Analysis of
Permanent Rule Adoption with No Substantial Economic Impact

Rule .1802 revised

Agency Proposing Rule Change
North Carolina Division of Health Service Regulation

Contact Persons
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Impact Summary

Federal Government Entities:	No Impact
State Government Entities:	No Impact
Local Government Entities:	No Impact
Small Business:	No Impact
Substantial Impact:	No

Title of Rules Changes and Statutory Citations

10A NCAC 14F

Section .1200 -- Certification
- Certificate Renewal 10A NCAC 14F .1203 (Readopt)

Section .1300 – Administration
- Staff Requirements and Responsibilities 10A NCAC 14F .1301 (Readopt)

Section .1400 – Patient Rights
- Patient Rights 10A NCAC 14F .1401 (Amended)

Section .1800 – Provision of Services
- Exercise Therapy 10A NCAC 14F .1802 (Readopt)

Section .1900 -- Emergencies
- Emergency Drills 10A NCAC 14F .1903 (Readopt)

Section .2000 – Medical records
- Physical Environment and Equipment 10A NCAC 14F .2101 (Readopt)

See proposed text of these rules in Appendix 1

Statutory Authority

N.C.G.S. 131E-167-169

Background

Under authority of N.C.G.S. 150B-21-3A, Periodic review and expiration of existing rules, the Division of Health Service Regulation, Rules Review Commission and the Joint Legislative Administrative Procedure Oversight Committee approved the subchapter report with classifications for the rules located at 10A NCAC 14F—Rules for the Certification of Cardiac Rehabilitation Programs on August 31, 2016, November 17, 2016, and December 6, 2016, respectively. Five rules were determined as necessary with substantive change and therefore subject to redoption as new rules.

The following five rules are proposed for readoption with substantive change in this report: 10A NCAC 14F .1203, .1301, .1802, .1903, and 2101.

The following rule is proposed for amendment: 10A NCAC 14F .1401. This rule is being amended to update information in the rule.

The rule readoptions presented in this fiscal analysis will provide clarity, remove ambiguity, and implement several technical changes. Changes will also allow reference to the statute where appropriate. There are 77 licensed Cardiac Rehabilitation Facilities, all are certified. All the facilities currently renew their certificates annually at a cost of $385.00 per certificate.

A stakeholder group was formed to vet the rule revisions and to ensure revisions reflect current standards of practice. The stakeholder group is supportive of the proposed readoptions.

Rules Summary and Anticipated Fiscal Impact

Rule .1203 – Certificate Renewal
The agency is proposing to readopt this rule with substantive changes. Cardiac Rehab entities must be issued a certificate to operate their programs. These certificates must be renewed annually. This rule is being readopted with substantive changes to allow the cardiac rehab certificate to renew annually instead of every two years. The current rule allows the certificate to expire every two years and is in conflict with the statute; 131E-167(a). This change will bring the rule into compliance with the statute and with the current practice of renewing the certificate annually. Cardiac Rehab agencies have always followed the statue and renewed certificates annually for years. This will not be a change to their current practice. The rule is also being changed to reference the statue; G.S. 131E-167, instead of "pursuant to the Article" to remove ambiguity.

Rule .1202 was added as a reference to identify where the contents of the application can be found. There is no additional cost or expense associated with the rule change.

Fiscal Impact

There is no fiscal impact associated with the readoption of this rule.

Rule .1301 – Staff Requirements and Responsibilities
The agency is proposing to readopt this rule with substantive changes. This rule establishes staff requirements and responsibilities for the Cardiac Rehab program. The rule was changed to clarify that individuals with occupational licenses shall perform functions determined by their respective occupational licensing board, which has always been the practice. The state agency has no authority to determine their functions. This clarification is only applicable to staff linked to a licensing board. It won't apply to staff that aren't licensed. Unlicensed staff responsibilities are determined by the respective

hiring entity via position descriptions. There were also several technical changes made, ambiguity was removed, and clarifications were made in the rule language.

Fiscal Impact

There is no fiscal impact associated with the readoption of this rule.

Rule .1401 – Patient Rights
The agency is proposing to amend this rule. This rule establishes criteria for patient rights prior to and at the time of admission to the Cardiac Rehab program. This rule is being changed to remove ambiguity, clarify rule language, and a technical change is being made to clarify that complaints should be called into the Complaint Intake of the Division instead of the Careline. The Careline no longer exists.

Fiscal Impact

There is no fiscal impact associated with the amendment of this rule

Rule .1802 – Exercise Therapy
This rule is being readopted with substantive changes for clarity and to remove ambiguity. This rule establishes criteria for the Cardiac Rehab exercise therapy program. The changes are more up to date and will clarify what is included in the first exercise session, clarify the basics for exercise therapy by incorporating guidelines for exercise testing and prescription, will identify where a copy of the information can be obtained, and the cost. Some of the guidelines in the current rule have been revised. These guidelines are market driven and the state agency need to adopt the standards for enforcement and as a means of risk avoidance. These standards will help ensure the agency is maintaining and enforcing minimal standards. The guidelines are revised as standards of practice are changed. Adopting the guidelines by reference will prevent the agency from amending the rule each time the guidelines are revised. If the guidelines aren't adopted, the state agency won't be able to enforce the standards. There is no impact to Cardiac Rehab facilities. The guidelines are currently utilized by Cardiac Rehabilitation facilities.
Also, the Cardiac Rehabilitation program is currently required to monitor adherence to the cardiac rehabilitation plans and progress. There were changes made to clarify who should document the results of the monitoring and the policy that should be followed for documenting. There were also changes made to clarify who should document the patient's progress towards goals, the policy that should be followed while doing so, to clarify who the exercise specialist should consult with regarding treatment plan changes, and the process to follow after changes occur. There will be no impact to the facility as these are current practices. Additional changes identified what policy should be followed when determining abnormal blood sugars. These clarifications are a current practice.

Fiscal Impact

There is no fiscal impact associated with the readoption of this rule.

Rule .1903 -- Emergency Drills
This rule is being readopted with substantive changes. This rule establishes emergency drill requirements for Cardiac Rehab Programs. It is being changed to reduce the number of required patient emergency drills from at least six drills to quarterly drills as a result of CMS and accreditation changes. Some of the drills will be table top. For those that aren't tabletop there is no requirement to evacuate patients. The drills must include simulated conditions. Staff will participate in the drills in accordance with the facilities' response plan. Drills will be critiqued for evaluation purposes. There is no established requirement regarding the number of individuals needed to critique the drill or who those individuals

must be. Changes will also clarify drill documentation requirements. Cardiac Rehab stakeholders provided input to this change and stated that Cardiac Rehabilitation Program market conduct in excess of six emergency drills a year and will likely continue to do so.

Fiscal Impact

There is no fiscal impact associated with the readoption of this rule

Rule .2101 -- Physical Environment and Equipment
The agency is proposing to readopt this rule with substantive changes. This rule sets standards for Cardiac Rehab facilities and equipment. This change is necessary to ensure the agency can uphold and enforce minimum standards regarding physical environment and equipment. The rule clarifies cleaning standards for equipment and furnishing to per manufacturer's instructions or defaults to the Cardiac Rehabilitation Facility Program for infection control. Cardiac Rehabilitation programs are currently meeting manufacturer's requirements for cleaning, and currently have policies regarding infection control. These infection control policies have been in existence from the very beginning. The rules are minimum requirements for Cardiac Rehab Programs. Adopting these changes will make them enforceable and allow the agency to regulate. Technical changes were also made in the rule language.

Fiscal Impact

There is no fiscal impact associated with the readoption of this rule.

Appendix 1

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, ~~an~~d 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 amendments and editions. Copies of the American College of Sports Medicine guidelines are available from http://www.acsmstore.org/Product_Details.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~~ 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.~~ 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 .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.