RRC STAFF OPINION

PLEASE NOTE: THIS COMMUNICATION IS EITHER 1) ONLY THE RECOMMENDATION OF AN RRC STAFF ATTORNEY AS TO ACTION THAT THE ATTORNEY BELIEVES THE COMMISSION SHOULD TAKE ON THE CITED RULE AT ITS NEXT MEETING, OR 2) AN OPINION OF THAT ATTORNEY AS TO SOME MATTER CONCERNING THAT RULE. THE AGENCY AND MEMBERS OF THE PUBLIC ARE INVITED TO SUBMIT THEIR OWN COMMENTS AND RECOMMENDATIONS (ACCORDING TO RRC RULES) TO THE COMMISSION.

AGENCY: Division of Health Service Regulation

REPORT CITATION: 10A NCAC 14F

RECOMMENDED ACTION:

X Note staff's comment

X Designate Rule 10A NVCAC 14F .1203 as "necessary with substantive public interest."

COMMENT:

G.S. 150B-21.3A(a)(5) defines a public comment as "[W]ritten comments objecting to the Rule, in whole or in part[.]" G.S. 150B-21.3A(c)(2) states that if an agency receives written comments for a rule determined by the agency to be "unnecessary" or "necessary without substantive public interest," the Commission is to determine whether the comment has "merit." The statute states that a comment has merit if it relates to a specific substance of the rule and relates to any of the standards of review set forth in G.S. 150B-21.9(a).

For purposes of this Staff Opinion, the following exhibits are attached:

A. Report for 10A NCAC 14F
B. Comments and responses
C. Rules in 10A NCAC 14F
D. Article 8 of G.S. 131E
E. 42 CFR 410.49
F. Section 34.6 of S.L. 2003-284

The agency for the report 10A NCAC 14F, Division of Health Service Regulation, classified all 32 rules as "necessary without substantive public interest." After the comment period, the agency changed four rules to "necessary with substantive public interest." The agency received a comment that addressed all of the rules. The comment was from the North Carolina Cardiopulmonary Rehabilitation Association, and stated the following:

> [that all of the rules should] be deemed "Unnecessary". At the very least, NCCRA recommends that 10A NCAC 14F.1101-.2106 be revised to be in agreement with Title 42 Code of Federal Regulations, 42 CFR Section 410.49 Medicare conditions of coverage for cardiac rehabilitation programs and intensive cardiac rehabilitation programs.

Abigail M. Hammond
Commission Counsel

The agency responded to this singular comment as follows:

> The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR.
>
> Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.
>
> Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.

Based upon a review of the comment for all of the rules and the response of the agency, staff counsel does not recommend changing the final classification for any of the rules, with one exception. As indicated by the agency in their response, to claim these rules are unnecessary would be contrary to the directive from the General Assembly set forth in Article 8 in G.S. 131E. The agency cites the "Title; Purpose." in G.S. 131E-165. In addition to the agency's cited statute, G.S. 131E-169 requires the following:

> **§ 131E-169. Rules and enforcement.**
>
> (a) The Department is authorized to adopt, amend, and repeal all rules as may be designed to further the accomplishment of this Article.
>
> (b) The Department shall enforce the rules adopted for the certification of cardiac rehabilitation programs. (1983, c. 775, s. 1.)

In light of the General Assembly's statutory directive to the agency to promulgate rules for administration of cardiac rehabilitation programs, the rules in 10A NCAC 14F do appear to be necessary and staff counsel agrees that the agency should not have classified the rules as "unnecessary." The comment further references 42 CFR 410.49. Pursuant to G.S. 150B-21.6, agencies may incorporate portions of the Code of Federal Regulations into rules, but that decision falls within agency's determination of the quality and efficacy of a rule, and is outside the review of the Rules Review Commission, as set forth in G.S. 150B-21.9(a). Therefore, it is staff's recommendation to not change the final classification of all rules classified as "necessary without substantial public interest," with the exception of Rule 10A NCAC 14F .1203. Rule 10A NCAC 14F .1203 is addressed at the bottom of this Staff Opinion on page five through six.

The agency did receive additional comments. Below is a summary:

Rule	Comment	Agency's Response	Staff Counsel's Recommendation
10A NCAC 14F .1206	Information in this section is for Inspection section not the Adverse Action information	The Agency determined this rule was necessary without substantive public interest. Based	The "Inspections" rule is 10A NCAC 14F .1205, and 10A NCAC 14F

		on the comment, we will not change the rule's categorization. The rule citation is incorrect for the comment submitted. This rule, 14F .1206, defines the various adverse actions / sanctions which could potentially be implemented consistent with GS 131E-168 and DHSR's standard operating procedures.	.1206 is "Adverse Action." No change is recommended for the agency's final classification.
10A NCAC 14A .1301 Rule reclassified to "necessary with substantive public interest."	--	--	--
10A NCAC 14F .1601	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' - add statement that this is implied when the Medical Director closes/signs the initial exercise prescription.	The Agency determined this rule was necessary without substantive public interest. We will not change the rule's categorization. The current rule is clear and allows the provider to develop policies that allow the attending physician or medical director to determine medical necessity for a graded exercise test. No change is recommended to the rule.	This comment does not appear to address the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9(a). No change is recommended for the agency's final classification.
10A NCAC 14F .1701	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' - Comment: For programs with EMR, care plans/individual treatment plans will be available in the system for all physicians to view.	The Agency determined this rule was necessary without substantive public interest. We will not change the rule's categorization. The intent of the current rule is clear and it is to provide the personal and referring physician access to the patient's	This comment does not appear to address the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9(a). No change is recommended for

		treatment plan via the least costly mode. No change is recommended to the rule.	the agency's final classification.
10A NCAC 14F .1702	As an AACVPR certified Cardiac Rehab Facility, we appreciate the opportunity to review and make comments to the current North Carolina Statute pertaining to Outpatient Cardiac Rehab Services. While we appreciate the importance of Interdisciplinary Team Meetings, the ability to follow the patient's progress of goals can be monitored collaboratively with the use of the ITP (Individualized Treatment Plans), mandated by CMS in 2010. All disciplines use the tool to document required core components to measure patient's progress, reviewed and signed by the Medical Director upon admission, every 30 days and at discharge. The use of the ITP has been an asset to the Cardiac Rehab program and promotes ongoing interdisciplinary collaboration. When used appropriately this would necessitate concurrent evaluation and reevaluation of the patient's plan of care with the patient's input which is then recorded in the patient record. Team interaction, discussions, and updates to the patient's plan of care are parallel to the cardiac rehab sessions. With this said, could consideration be given for the use of the ITP tool as a replacement for monthly interdisciplinary meetings?	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The agency supports the concept and practice of interdisciplinary care planning rather than ITP. The current rule allows the licensed entity to develop policies and have the flexibility to define the appropriate tool for documentation.	This comment does not appear to address the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9(a). No change is recommended for the agency's final classification.
10A NCAC 14A .1801	The addition of non physician providers as appropriate personnel to supervise the program is an excellent step in creating greater access to care for patients.	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will not change the rule's categorization. The rule currently allows for non-physician	This comment does not appear to address the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9(a). No

		providers.	change is recommended for the agency's final classification.
10A NCAC 14A .1802 Rule reclassified to "necessary with substantive public interest."	--	--	--
10A NCAC 14A .1901 Rule reclassified to "necessary with substantive public interest."	--	--	--
10A NCAC 14A .1902	Remove intubation equipment requirement.	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will not change the rule's categorization. The agency will not remove this requirement in the rule as it is needed for safe practice in the event of resuscitation of patients.	This comment does not appear to address the standards for review by the Rules Review Commission set forth in G.S. 150B-21.9(a). No change is recommended for the agency's final classification.

For a separate rule, 10A NCAC 14F .1203, staff counsel recommends a change to the classification of this Rule. Rule 10A NCAC 14F .1203 addresses "Certificate Renewal" and states that a "certificate issued pursuant to the Article and this Subchapter shall expire two years after the effective date." The cited authority for this Rule is G.S. 131E-167 and G.S. 131E-169. This Rule became effective on July 1, 2000. However, section 34.6 of S.L. 2003-284 amended G.S. 131E-167 as follows:

> G.S. 131E-167(a) reads as rewritten:
> "(a) Applications for certification shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A certificate shall be granted to the applicant for a period not to exceed ~~two years~~one year upon a determination by the Department that the applicant has substantially complied with the provisions of this Article and the rules

promulgated by the Department under this Article. The Department shall charge the applicant a nonrefundable annual certification fee in the amount of one hundred twenty-five dollars ($125.00)."

In light of the statutory change made in 2003, Rule 10A NCAC 14F .1203 as written lacks statutory authority. The agency many not grant certifications for a two-year period, as reflected in Paragraph (a) of this Rule. The certifications, in compliance with G.S. 131E-167(a), may only be issued for one year. Therefore, it is staff counsel's recommendation to change the classification of 10A NCAC 14F .1203, as the current language does not comply with the statutory authority granted to the agency by the General Assembly.

EXHIBIT A

G.S. 150B-21.3A Report for SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS

Agency - DHHS/Division of Health Service Regulation

Comment Period - 03/21/16 - 05/20/16

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS	**SECTION .1100 – GENERAL INFORMATION: DEFINITIONS**	10A NCAC 14F .1101	DEFINITIONS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1200 – CERTIFICATION	10A NCAC 14F .1201	CERTIFICATE	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1202	CERTIFICATION PROCESS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1203	CERTIFICATE RENEWAL	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1204	CERTIFICATION FOLLOWING PROGRAM CHANGES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1205	INSPECTIONS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1206	ADVERSE ACTION	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1300 – ADMINISTRATION	10A NCAC 14F .1301	STAFF REQUIREMENTS AND RESPONSIBILITIES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary with substantive public interest
		10A NCAC 14F .1302	POLICIES AND PROCEDURES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1303	CONTINUOUS QUALITY IMPROVEMENT	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1400 – PATIENT RIGHTS	10A NCAC 14F .1401	PATIENT RIGHTS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1500 – ADMISSION AND DISCHARGE	10A NCAC 14F .1501	ADMISSION AND DISCHARGE	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1600 – PATIENT ASSESSMENT	10A NCAC 14F .1601	PATIENT ASSESSMENT	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest

G.S. 150B-21.3A Report for SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS

Agency - DHHS/Division of Health Service Regulation

Comment Period - 03/21/16 - 05/20/16

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
	SECTION .1700 – CARE PLANNING AND FOLLOW-UP EVALUATION	10A NCAC 14F .1701	CARE PLANNING	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1702	FOLLOW-UP EVALUATION	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1800 – PROVISION OF SERVICES	10A NCAC 14F .1801	PERSONNEL	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1802	EXERCISE THERAPY	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary with substantive public interest
		10A NCAC 14F .1803	NUTRITION SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1804	MENTAL HEALTH SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1805	VOCATIONAL REHABILITATION COUNSELING AND SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1806	PATIENT EDUCATION	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .1900 – EMERGENCIES	10A NCAC 14F .1901	EMERGENCY PLAN	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary with substantive public interest
		10A NCAC 14F .1902	EMERGENCY EQUIPMENT	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .1903	EMERGENCY DRILLS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .2000 – MEDICAL RECORDS	10A NCAC 14F .2001	POLICIES AND PROCEDURES FOR MEDICAL RECORDS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .2002	CONTENT OF MEDICAL RECORDS	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
	SECTION .2100 – FACILITIES AND EQUIPMENT	10A NCAC 14F .2101	PHYSICAL ENVIRONMENT AND EQUIPMENT	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary with substantive public interest
		10A NCAC 14F .2102	GRADED EXERCISE TESTING LABORATORY	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest

G.S. 150B-21.3A Report for SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS

Agency - DHHS/Division of Health Service Regulation

Comment Period - 03/21/16 - 05/20/16

Date Submitted to APO - Filled in by RRC staff

Subchapter	Rule Section	Rule Citation	Rule Name	Date and Last Agency Action on the Rule	Agency Determination [150B-21.3A(c)(1)a]	Implements or Conforms to Federal Regulation [150B-21.3A(e)]	Federal Regulation Citation	Public Comment Received [150B-21.3A(c)(1)]	Agency Determination Following Public Comment [150B-21.3A(c)(1)]
		10A NCAC 14F .2103	EXERCISE THERAPY	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .2104	NUTRITION SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .2105	MENTAL HEALTH SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest
		10A NCAC 14F .2106	VOCATIONAL REHABILITATION SERVICES	Eff. July 1, 2000	Necessary without substantive public interest	No		Yes	Necessary without substantive public interest

EXHIBIT B

Periodic Rules Review and Expiration of Existing Rules
Subchapter 14F – Certification of Cardiac Rehabilitation Programs
Public Comments and Agency Response to Comments

Rule Citation & Title	Date	Commenter	Comment	Agency Response
1) 10A NCAC 14F .1101 – Definitions	3/17/16	1a) Erin Glendening, DHSR erin.glendening@dhhs.nc.gov	This is a test of the system.	The Agency determined this rule was necessary without substantive public interest. The comment is about the test of the electronic comment reporting system. Based on the comment, we will not change the rule's categorization.
		1b) Debbie Scotten, North Carolina Cardiopulmonary Rehabilitation Association Debbie.Scotten@unchealth.unc.edu	North Carolina Cardiopulmonary Rehabilitation Association Response to DHHS Review of 10A NCAC 14F.1101 - .2106 Certification of Cardiac Rehabilitation Programs The North Carolina Cardiopulmonary Rehabilitation Association (NCCRA), representing over 70 cardiac rehabilitation programs in North Carolina, recommends that 10A NCAC 14F.1101 - .2106 Certification of Cardiac Rehabilitation Programs be deemed 'Unnecessary'. At the very least, NCCRA recommends that 10A NCAC 14F.1101-.2106 be revised to be in agreement with Title 42 Code of Federal Regulations, 42 CFR Section 410.49 Medicare conditions of coverage for cardiac rehabilitation programs and intensive cardiac rehabilitation programs. 10A NCAC 14F.1101-.2106 was last updated July 1, 2000. Since that time other, more current guidelines and rules governing the practice of cardiac rehabilitation have been developed and are in effect across the country. These include: - American Association for Cardiac and Pulmonary Rehabilitation. Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs, 5th Edition. Champaign, IL: Human Kinetics, 2013. Provides national certification for cardiac and pulmonary rehabilitation programs. - Title 42 Code of Federal Regulations, 42 CFR Section 410.49: Medicare conditions of coverage for cardiac rehabilitation program and intensive cardiac	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			rehabilitation program. http://edocket.access.gpo.gov/cfr_2010/octqtr/pdf/42 cfr410.49.pdf. - Local Coverage Determination for Cardiac Rehabilitation (L34412). https://www.cms.gov/medicare-coverage-database/details/lcd-details.... Last updated 1/14/2016. NCCRA recognizes that the science of cardiac rehabilitation is rapidly evolving and cardiac rehabilitation programs must have the ability to transition scientific knowledge to practice in a timely manner in order for patients to receive safe, efficient and effective care. The review process now in effect for rules regulating Certification of Cardiac Rehabilitation Programs at https://www2.ncdhhs.gov/dhsr/rules/index.html calls for review of the rules every ten (10) years. NCCRA does not believe this extended period of review is warranted and in the best interest of North Carolina's citizens. Thank you for the opportunity to respond to this rule on behalf of the North Carolina Cardiopulmonary Rehabilitation Association. Debbie Scotten, RN, MS, ACSM-CES, CCRP President, North Carolina Cardiopulmonary Rehabilitation Association Program Director, Cardiopulmonary Rehabilitation Chatham Hospital 475 Progress Blvd Siler City, NC 27344 919.799.4652 Cell: 919-200-1661	
2) 10A NCAC 14F .1201 – Certificate	5/17/16		Please see my comment under Definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines minimal information to be displaced on the state issued certificate which is consistent with DHSR standard operating procedures.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
3) 10A NCAC 14F .1202 – Certification Process	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines the application process prior to issuance of a certificate to operate which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
4) 10A NCAC 14F .1203 – Certificate Renewal	5/17/16	4a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines the licensure renewal application process

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/17/16	4b) ,	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines the licensure renewal application process which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/17/16	4c)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				The referenced rule defines the licensure renewal application process which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
5) 10A NCAC 14F .1204 – Certification Following Program Changes	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines the licensure application process for change (eg. ownership, address) which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
6) 10A NCAC 14F .1205 – Inspections	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The referenced rule defines the survey process which is consistent with DHSR standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
7) 10A NCAC 14F .1206 – Adverse Action	4/5/16	7a) Theresa Redmond,	Information in this section is for Inspection section not the Adverse Action information	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The rule citation is incorrect for the comment submitted. This rule, 14F .1206, defines the various adverse actions / sanctions which could potentially be implemented consistent with GS 131E-168 and DHSR's standard operating procedures.
	5/17/16	7b)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. The referenced rule defines the various adverse actions/sanctions which could potentially be implemented consistent with GS 131E-168 and DHSR's standard operating procedures. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
8) 10A NCAC 14F. 1301 – Staff Requirements and Responsibilities	4/14/16	8a)	Consider changing the title of Exercise Specialist to Exercise Physiologist to reflect the change made by American College of Sports Medicine (ACSM). Also consider providing qualifications for Exercise Physiologist, as required education and certification is not standard across the state.	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will change the rule's categorization to necessary with substantive public interest. We have noted the comment on changing exercise specialist to exercise physiologist with qualifications for the exercise physiologist. Additional research is needed to determine if a change in position is essential and if qualifications will be costly for providers. This will

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				be taken into consideration when the rule is revised.
	5/17/16	8b)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
9) 10A NCAC 14F .1302 – Policies and Procedures	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
10) 10A NCAC 14F .1303 – Continuous Quality Improvement	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
11) 10A NCAC 14F .1401 – Patient Rights	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
12) 10A NCAC 14F .1501 – Admission and Discharge	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
13) 10A NCAC 14F .1601 – Patient Assessment	5/17/16	13a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/19/16	13b) Karen	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;	The Agency determined this rule was necessary without substantive public interest. We will not change the rule's categorization. The current rule is clear and allows the provider to develop policies that allow the attending physician or medical director to determine medical necessity for a graded exercise test. No change is recommended to the rule.
	5/19/16	13c) Karen Craig, Duke karen.craig@duke.edu	'A graded exercise test shall not be required when deemed unnecessary by the patient's attending or	The Agency determined this rule was necessary without substantive public

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			personal physician or the program's medical director' - add statement that this is implied when the Medical Director closes/signs the initial exercise prescription	interest. We will not change the rule's categorization. The current rule is clear and allows the provider to develop policies that allow the attending physician or medical director to determine medical necessity for a graded exercise test. No change is recommended to the rule.
14) 10A NCAC 14F .1701 – Care Planning	5/17/16	14a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/19/16	14b) Karen Craig, Duke karen.craig@duke.edu	'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' - Comment: For programs with EMR, care plans/individual treatment plans will be available in the system for all physicians to view.	The Agency determined this rule was necessary without substantive public interest. We will not change the rule's categorization. The intent of the current rule is clear and it is to provide the personal and referring physician access to the patient's treatment plan via the

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				least costly mode. No change is recommended to the rule.
15) 10A NCAC 14F .1702 – Follow-up Evaluation	5/17/16	15a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
		15b)	As an AACVPR certified Cardiac Rehab Facility, we appreciate the opportunity to review and make comments to the current North Carolina Statute pertaining to Outpatient Cardiac Rehab Services. While we appreciate the importance of Interdisciplinary Team Meetings, the ability to follow the patient's progress of goals can be monitored collaboratively with the use of the ITP (Individualized Treatment Plans), mandated by CMS in 2010. All disciplines use the tool to document required core components to measure patient's progress, reviewed and signed by the Medical Director upon admission, every 30 days and at discharge. The use of the ITP has	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. The agency supports the concept and practice of interdisciplinary care planning rather than ITP. The current rule allows the licensed entity to develop policies and have the flexibility to define the appropriate tool for documentation.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			been an asset to the Cardiac Rehab program and promotes ongoing interdisciplinary collaboration. When used appropriately this would necessitate concurrent evaluation and reevaluation of the patient's plan of care with the patient's input which is then recorded in the patient record. Team interaction, discussions, and updates to the patient's plan of care are parallel to the cardiac rehab sessions. With this said, could consideration be given for the use of the ITP tool as a replacement for monthly interdisciplinary meetings?	
16) 10A NCAC 14F .1801 - Personnel	4/1/16	16a) Janis McLaughlin, WakeMed jamclaughlin@wakemed.org	The addition of non physician providers as appropriate personnel to supervise the program is an excellent step in creating greater access to care for patients.	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will not change the rule's categorization. The rule currently allows for non-physician providers.
	5/17/16	16b) ,	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
17) 10A NCAC 14F .1802 – Exercise Therapy	5/19/16	17a) ,	Comments: Use ACSM's guidelines for exercise prescription (9th edition, 2014): *Based on results from the baseline exercise test, 40%-80% of exercise capacity, using heart rate reserve, oxygen uptake reserve or peak oxygen uptake methods. *RPE of 11-16 on a scale of 6-20 *Exercise intensity should be prescribed at a HR below the ischemic threshold *For patients without an entry exercise test, exercise prescription procedures can be based on the recommendations of the above guidelines and what was established during the inpatient phase, home exercise activities and RPE. Use objective assessment (6' walk or cycle test) for staff to develop and modify a specific exercise prescription. *Allow patients to come 1-5 times per week (based on Medicare's rule) *Allow exercise physiologists flexibility to prescribe appropriate exercise for each patient, based on signs and symptoms and patient's current state of training.	The Agency determined rule .1802 was necessary without substantive public interest. Based on the comment, we will change the rule's categorization to necessary with substantive public interest. We have noted the comment to be consistent with current standards of practice. This comment will be taken into consideration when the rule is revised.
	5/19/16	17b) Karen Craig, Duke karen.craig@duke.edu	Comments: Use ACSM's guidelines for exercise prescription (9th edition, 2014): *Based on results from the baseline exercise test, 40%-80% of exercise capacity, using heart rate reserve, oxygen uptake reserve or peak oxygen uptake methods. *RPE of 11-16 on a scale of 6-20 *Exercise intensity should be prescribed at a HR below the ischemic threshold *For patients without an entry exercise test, exercise prescription procedures can be based on the recommendations of the above guidelines and what was established during the inpatient phase, home exercise activities and RPE. Use objective assessment (6' walk or cycle test) for staff to develop and modify a specific exercise prescription. *Allow patients to come 1-5 times per week (based on Medicare's rule) *Allow exercise physiologists flexibility to prescribe	The Agency determined rule .1802 was necessary without substantive public interest. Based on the comment, we will change the rule's categorization to necessary with substantive public interest. We have noted the comment to be consistent with current standards of practice. This comment will be taken into consideration when the rule is revised.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
			appropriate exercise for each patient, based on signs and symptoms and patient's current state of training.	
18) 10A NCAC 14F .1803 – Nutrition Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
19) 10A NCAC 14F .1804 – Mental Health Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
20) 10A NCAC 14F .1805 – Vocational Counseling and Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
21) 10A NCAC 14F .1806 – Patient Education	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
22) 10A NCAC 14F .1901 – Emergency Plan	5/17/16	22a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/19/16	22b)	We would recommend updating the emergency drills to follow AACVPR guideline requirements for 4 patient emergency drills annually.	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will change the rule's categorization to necessary with substantive public interest. We have noted the comment to reduce the number of emergency drills from six to four emergency drills each year is consistent with current standards of practice. This comment will be taken into consideration when the rule is revised.
23) 10A NCAC 14F .1902 – Emergency Equipment	5/17/16	23a)	Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
	5/19/16	23b)	Remove intubation equipment requirement	The Agency determined this rule was necessary without substantive public interest. Based on this comment, we will not change the rule's categorization. The agency will not remove this requirement in the rule as it is needed for safe practice in the event of resuscitation of patients.
24) 10A NCAC 14F .1903 – Emergency Drills	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
25) 10A NCAC 14F .2001 – Policies and Procedures for	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42

Rule Citation & Title	Date	Commenter	Comment	Agency Response
Medical Records				CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
26) 10A NCAC 14F .2002 – Content of Medical Records	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
27) 10A NCAC 14F .2101 – Physical Environment and Equipment	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will change the rule's categorization to necessary with substantive public interest. In reviewing the rule, it does not meet the current CDC infection control practice guidelines, therefore, we will take this into consideration during rule revision. Comments requesting revision to be in agreement with 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
28) 10A NCAC 14F .2102 – Graded Exercise	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare

Rule Citation & Title	Date	Commenter	Comment	Agency Response
Testing Laboratory				conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
29) 10A NCAC 14F .2103 – Exercise Therapy	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
30) 10A NCAC 14F .2104 – Nutrition Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
31) 10A NCAC 14F .2105 – Mental Health Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR.

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.
32) 10A NCAC 14F .2106 – Vocational Rehabilitation Services	5/17/16		Please see my comment under definitions. Debbie Scotten	The Agency determined this rule was necessary without substantive public interest. Based on the comment, we will not change the rule's categorization. 42 CFR Section 410.49 Medicare conditions for coverage for cardiac rehabilitation and intensive cardiac rehabilitation programs defines parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR. Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program. Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.

SUBCHAPTER 14F- CERTIFICATION OF CARDIAC REHABILITATION PROGRAMS

EXHIBIT C

SECTION .0100 – RESERVED FOR FUTURE CODIFICAITON
SECTION .0200 – RESERVED FOR FUTURE CODIFICATION

SECTION .0300 – RESERVED FOR FUTURE CODIFICATION

SECTION .0400 – RESERVED FOR FUTURE CODIFICATION

SECTION .0500 – RESERVED FOR FUTURE CODIFICATION

SECTION .0600 – RESERVED FOR FUTURE CODIFICATION

SECTION .0700 – RESERVED FOR FUTURE CODIFICATION

SECTION .0800 – RESERVED FOR FUTURE CODIFICATION

SECTION .0900 – RESERVED FOR FUTURE CODIFICATION

SECTION .1000 – RESERVED FOR FUTURE CODIFICATION

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**~~

Classified as "necessary with"

(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.

Classified as "necessary with"

~~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~~

Classified as "necessary with"

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

Classified as "necessary with"

~~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.

EXHIBIT D

Article 8.

Cardiac Rehabilitation Certification Program.

§ 131E-165. Title; purpose.

(a) This Article shall be known as the "Cardiac Rehabilitation Certification Program."

(b) The purpose of this Article is to provide for the development, establishment, and enforcement of rules and certification:

(1) For the care and treatment of individuals in outpatient cardiac rehabilitation programs; and

(2) For the maintenance and operation of cardiac rehabilitation programs to ensure safe and adequate treatment of individuals in cardiac rehabilitation programs. (1983, c. 775, s. 1; 1995, c. 182, s. 1.)

§ 131E-166. Definitions.

As used in this Article, unless otherwise specified:

(1) "Cardiac Rehabilitation Program" means a program certified under this Article for the delivery of cardiac rehabilitation services to outpatients and includes, but shall not be limited to, coordinated, physician-directed, individualized programs of therapeutic activity and adaption designed to assist the cardiac patient in attaining the highest rehabilitative potential.

(2) "Certification" means the issuance of a certificate by the Department upon determination that cardiac rehabilitation services offered at a given program site meet all cardiac rehabilitation program rules. (1983, c. 775, s. 1; 1995, c. 182, s. 2.)

§ 131E-167. Certificate requirement.

(a) Applications for certification shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A certificate shall be granted to the applicant for a period not to exceed one year upon a determination by the Department that the applicant has substantially complied with the provisions of this Article and the rules promulgated by the Department under this Article. The Department shall charge the applicant a nonrefundable annual certification fee in the amount of three hundred eighty-five dollars ($385.00).

(b) A provisional certificate may be issued for a period not to exceed six months to a program:

(1) That does not substantially comply with the rules, when failure to comply does not endanger the health, safety, or welfare of the clients being served by the program;

(2) During the initial stages of operation if determined appropriate by the Department.

(c) Prior to offering a cardiac rehabilitation program as defined in this Article, such a program must be inspected, evaluated, and certified as having substantially met the rules adopted by the Department under this Article.

(d) A certificate to operate a Cardiac Rehabilitation Program shall be renewed upon the successful re-evaluation of the program as stated in the rules adopted pursuant to this Article.

(e) Each certificate shall be issued only for the premises and persons named in the application and shall not be transferable or assignable except with the written approval of the Department.

(f) A certificate shall be posted in a conspicuous place on the certified premises. (1983, c. 775, s. 1; 2003-284, s. 34.6(a); 2005-276, s. 41.2(f); 2009-451, s. 10.76(c).)

§ 131E-168. Adverse action on a certificate.

(a) Subject to subsection (b), the Department is authorized to deny a new or renewal certificate and to suspend or revoke an existing certificate upon determination that there has been a substantial failure to comply with the provisions of this Article or the rules promulgated under this Article.

(b) The provisions of Chapter 150A of the General Statutes, the Administrative Procedure Act, shall govern all administrative action and judicial review in cases where the Department has taken the action described in subsection (a). (1983, c. 775, s. 1.)

§ 131E-169. Rules and enforcement.

(a) The Department is authorized to adopt, amend, and repeal all rules as may be designed to further the accomplishment of this Article.

(b) The Department shall enforce the rules adopted for the certification of cardiac rehabilitation programs. (1983, c. 775, s. 1.)

§ 131E-170. Inspections.

(a) The Department shall make or cause to be made inspections of Cardiac Rehabilitation Programs as it deems necessary. The Department is empowered to delegate to a State officer, agent, board, bureau or division of State government the authority to make these inspections according to the rules promulgated by the Department. In addition, an individual who is not a State officer or agent and who is delegated the authority to make these inspections must be approved by the Department. The Department may revoke this delegated authority in its discretion.

(b) Notwithstanding the provisions of G.S. 8-53, "Communications between physician and patient," or any other provision of law relating to the confidentiality of communications between physician and patient, the representatives of the Department who make these inspections may review any writing or other record in any recording medium which pertains to the admission, discharge, medication, treatment, medical condition, or history of persons who are or have been patients of the program being inspected unless that patient objects in writing to review of that patient's records. Physicians, psychiatrists, nurses, and anyone else involved in giving treatment at or through a program who may be interviewed by representatives of the Department may disclose to these representatives information related to any inquiry, notwithstanding the existence of the physician-patient privilege in G.S. 8-53, "Communication between physician and patient," or any other rule of law, provided the patient has not made written objection to this disclosure. The program, its employees, and any person interviewed during these inspections shall be immune from liability for damages resulting from the disclosure of any information to the Department. Any confidential or privileged information received from review of records or interviews shall be kept confidential by the Department and not disclosed without written authorization of the patient or legal representative, or unless disclosure is ordered by a court of competent jurisdiction. The Department shall institute appropriate policies and procedures to ensure that this information shall not be disclosed without authorization or court order. The Department shall not disclose the name of anyone who has furnished information concerning a facility without the consent of that person. Neither the names of persons furnishing information nor any confidential or privileged information obtained from records or interviews shall be considered "public records" within the meaning of G.S. 132-1, "'Public records' defined." Prior to releasing any information or allowing any inspections referred to in this section, the patient must be advised in writing by the program that the patient has the right to object in writing to the release of information or review of the records and that by an objection in writing the patient may prohibit the inspection or release of the records. (1983, c. 775, s. 1.)

§§ 131E-171 through 131E-174. Reserved for future codification purposes.

EXHIBIT E

Part B makes payment for up to 6 sessions of kidney disease patient education services.

(2) A session is 1 hour long and may be provided individually or in group settings of 2 to 20 individuals who need not all be Medicare beneficiaries.

(f) *Effective date.* Medicare Part B covers kidney disease patient education services for dates of service on or after January 1, 2010.

[74 FR 62003, Nov. 25, 2009]

§ 410.49 Cardiac rehabilitation program and intensive cardiac rehabilitation program: Conditions of coverage.

(a) *Definitions.* As used in this section:

Cardiac rehabilitation (CR) means a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, psychosocial assessment, and outcomes assessment.

Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:

(i) A description of the individual's diagnosis.

(ii) The type, amount, frequency, and duration of the items and services furnished under the plan.

(iii) The goals set for the individual under the plan.

Intensive cardiac rehabilitation (ICR) program means a physician-supervised program that furnishes cardiac rehabilitation and has shown, in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in paragraph (c) of this section.

Intensive cardiac rehabilitation site means a hospital outpatient setting or physician's office that is providing intensive cardiac rehabilitation utilizing an approved ICR program.

Medical director means a physician that oversees or supervises the cardiac rehabilitation or intensive cardiac rehabilitation program at a particular site.

Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes all of the following:

(i) Minimally, assessments from the commencement and conclusion of cardiac rehabilitation and intensive cardiac rehabilitation, based on patient-centered outcomes which must be measured by the physician immediately at the beginning of the program and at the end of the program.

(ii) Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.

Physician means a doctor of medicine or osteopathy as defined in section 1861(r)(1) of the Act.

Physician-prescribed exercise means aerobic exercise combined with other types of exercise (that is, strengthening, stretching) as determined to be appropriate for individual patients by a physician.

Psychosocial assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation which includes an assessment of those aspects of an individual's family and home situation that affects the individual's rehabilitation treatment, and psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under cardiac rehabilitation and intensive cardiac rehabilitation programs.

(b) *General rule*—(1) *Covered beneficiary rehabilitation services.* Medicare part B covers cardiac rehabilitation and intensive cardiac rehabilitation program services for beneficiaries who have experienced one or more of the following:

(i) An acute myocardial infarction within the preceding 12 months;

(ii) A coronary artery bypass surgery;

(iii) Current stable angina pectoris;

(iv) Heart valve repair or replacement;

(v) Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;

(vi) A heart or heart-lung transplant.

(vii) For cardiac rehabilitation only, other cardiac conditions as specified

through a national coverage determination.

(2) *Components of a cardiac rehabilitation program and an intensive cardiac rehabilitation program.* Cardiac rehabilitation programs and intensive cardiac rehabilitation programs must include all of the following:

(i) Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.

(ii) Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to the patients' individual needs.

(iii) Psychosocial assessment.

(iv) Outcomes assessment.

(v) An individualized treatment plan detailing how components are utilized for each patient. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

(3) *Settings.* (i) Medicare Part B pays for cardiac rehabilitation and intensive cardiac rehabilitation in one of the following settings:

(A) A physician's office.

(B) A hospital outpatient setting.

(ii) All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items and services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision for physician office services, at §410.26 of this subpart; and for hospital outpatient services at §410.27 of this subpart.

(c) *Standards for an intensive cardiac rehabilitation program.* (1) To be approved as an intensive cardiac rehabilitation program, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

(i) Positively affected the progression of coronary heart disease.

(ii) Reduced the need for coronary bypass surgery.

(iii) Reduced the need for percutaneous coronary interventions;

(2) An intensive cardiac rehabilitation program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in 5 or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services:

(i) Low density lipoprotein.

(ii) Triglycerides.

(iii) Body mass index.

(iv) Systolic blood pressure.

(v) Diastolic blood pressure.

(vi) The need for cholesterol, blood pressure, and diabetes medications.

(3) A list of approved intensive cardiac rehabilitation programs, identified through the national coverage determination process, will be posted to the CMS Web site and listed in the FEDERAL REGISTER.

(4) All prospective intensive cardiac rehabilitation sites must apply to enroll as an intensive cardiac rehabilitation program site using the designated forms as specified at §424.510 of this chapter. For purposes of appealing an adverse determination concerning site approval, an intensive cardiac rehabilitation site is considered a supplier (or prospective supplier) as defined in §498.2 of this chapter.

(d) *Standards for the physician responsible for cardiac rehabilitation program.* A physician responsible for a cardiac rehabilitation program or intensive cardiac rehabilitation programs is identified as the medical directors. The medical director, in consultation with staff, are involved in directing the progress of individuals in the program, must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the cardiac rehabilitation program is offered.

(e) *Standards for supervising-physicians.* Physicians acting as the supervising-physician must possess all of the following:

(1) Expertise in the management of individuals with cardiac pathophysiology.

(2) Cardiopulmonary training in basic life support or advanced cardiac life support.

(3) Be licensed to practice medicine in the State in which the cardiac rehabilitation program is offered.

(f) *Limitations for coverage of cardiac rehabilitation programs.* (1) *Cardiac Rehabilitation:* The number of cardiac rehabilitation program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the Medicare contractor under section 1862(a)(1)(A) of the Act.

(2) *Intensive Cardiac Rehabilitation:* Intensive cardiac rehabilitation program sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

[74 FR 62003, Nov. 25, 2009]

§ 410.50 Institutional dialysis services and supplies: Scope and conditions.

Medicare Part B pays for the following institutional dialysis services and supplies if they are furnished in approved ESRD facilities:

(a) All services, items, supplies, and equipment necessary to perform dialysis and drugs medically necessary and the treatment of the patient for ESRD and, as of January 1, 2011, renal dialysis services as defined in § 413.171 of this chapter.

(b) Routine dialysis monitoring tests (i.e., hematocrit and clotting time) used by the facility to monitor the patients' fluids incident to each dialysis treatment, when performed by qualified staff of the facility under the direction of a physician, as provided in § 494.130 of this chapter, even if the facility does not meet the conditions for coverage of services of independent laboratories in part 494 of this chapter.

(c) Routine diagnostic tests.

(d) Epoetin (EPO) and its administration.

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 1285, Jan. 10, 1994; 73 FR 20474, Apr. 15, 2008; 75 FR 49197, Aug. 12, 2010]

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:

(1) Purchase or rental, installation, and maintenance of all dialysis equipment necessary for home dialysis, and reconditioning of this equipment. Dialysis equipment includes, but is not limited to, artificial kidney and automated peritoneal dialysis machines, and support equipment such as blood pumps, bubble detectors, and other alarm systems.

(2) Items and supplies required for dialysis, including (but not limited to) dialyzers, syringes and needles, forceps, scissors, scales, sphygmomanometer with cuff and stethoscope, alcohol wipes, sterile drapes, and rubber gloves.

(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis.

(4) On or after July 1, 1991, erythropoeisis-stimulating agents for use at home by a home dialysis patient and, on or after January 1, 1994, by a dialysis patient, if it has been determined, in accordance with § 494.90(a)(4) of this chapter, that the patient is competent to use the drug safely and effectively.

(b) Home dialysis support services specified in paragraph (a)(3) of this section must be furnished in accordance with a written treatment plan that is prepared and reviewed by a team consisting of the individual's physician and other qualified professionals. (Section 494.90 of this chapter contains details on patient plans of care).

[51 FR 41339, Nov. 14, 1986, as amended at 56 FR 43709, Sept. 4, 1991; 59 FR 26959, May 25, 1994; 73 FR 20474, Apr. 15, 2008]

§ 410.55 Services related to kidney donations: Conditions.

Medicare Part B pays for medical and other health services covered under this subpart that are furnished in connection with a kidney donation—

EXHIBIT F

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2003

SESSION LAW 2003-284
HOUSE BILL 397

AN ACT TO APPROPRIATE FUNDS FOR CURRENT OPERATIONS AND CAPITAL IMPROVEMENTS FOR STATE DEPARTMENTS, INSTITUTIONS, AND AGENCIES, AND FOR OTHER PURPOSES, AND TO IMPLEMENT A STATE BUDGET THAT ENABLES THE STATE TO PROVIDE A SUSTAINABLE RECOVERY THROUGH STRONG EDUCATIONAL AND ECONOMIC TOOLS.

The General Assembly of North Carolina enacts:

PART I. INTRODUCTION AND TITLE OF ACT

INTRODUCTION

SECTION 1.1. The appropriations made in this act are for maximum amounts necessary to provide the services and accomplish the purposes described in the budget. Savings shall be effected where the total amounts appropriated are not required to perform these services and accomplish these purposes and, except as allowed by the Executive Budget Act, or this act, the savings shall revert to the appropriate fund at the end of each fiscal year.

TITLE OF ACT

SECTION 1.2. This act shall be known as the "Current Operations and Capital Improvements Appropriations Act of 2003."

PART II. CURRENT OPERATIONS AND EXPANSION/GENERAL FUND

CURRENT OPERATIONS AND EXPANSION/GENERAL FUND

SECTION 2.1. Appropriations from the General Fund of the State for the maintenance of the State departments, institutions, and agencies, and for other purposes as enumerated, are made for the biennium ending June 30, 2005, according to the following schedule:

Current Operations - General Fund	**2003-2004**	**2004-2005**
EDUCATION		
Community Colleges System Office	660,927,719	660,199,222
Department of Public Instruction	6,035,050,302	6,034,995,183
University of North Carolina - Board of Governors	1,792,141,661	1,822,426,657
HEALTH AND HUMAN SERVICES		
Department of Health and Human Services Office of the Secretary	82,168,433	80,968,433

nonrefundable annual base license fee plus a nonrefundable annual per-bed fee as follows:

Facility Type	Number of Beds	Base Fee	Per-Bed Fee
General Acute Hospitals:	1-49 beds	$125.00	$6.25
	50-99 beds	$175.00	$6.25
	100-199 beds	$225.00	$6.25
	200-399 beds	$275.00	$6.25
	400-699 beds	$375.00	$6.25
	700+ beds	$475.00	$6.25
Other Hospitals:		$250.00	$6.25"

SECTION 34.2.(b) This section becomes effective October 1, 2003.

SECTION 34.3.(a) G.S. 131E-102(b) reads as rewritten:

"(b) Applications shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A license shall be granted to the applicant upon a determination by the Department that the applicant has complied with the provisions of this Part and the rules promulgated under this Part. The Department shall charge the applicant a nonrefundable annual license fee in the amount of two hundred twenty-five dollars ($225.00) plus a nonrefundable annual per-bed fee of six dollars and twenty-five cents ($6.25)."

SECTION 34.3.(b) This section becomes effective October 1, 2003.

SECTION 34.4.(a) G.S. 131E-138(c) reads as rewritten:

"(c) An application for a license shall be available from the Department, and each application filed with the Department shall contain all information requested by the Department. A license shall be granted to the applicant upon a determination by the Department that the applicant has complied with the provisions of this Part and the rules promulgated by the Commission under this Part. The Department shall charge the applicant a nonrefundable annual license fee in the amount of one hundred seventy-five dollars ($175.00)."

SECTION 34.4.(b) This section becomes effective October 1, 2003.

SECTION 34.5.(a) G.S. 131E-147(b) reads as rewritten:

"(b) Applications shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A license shall be granted to the applicant upon a determination by the Department that the applicant has complied with the provisions of this Part and the rules promulgated by the Commission under this Part. The Department shall charge the applicant a nonrefundable annual base license fee in the amount of three hundred fifty dollars ($350.00) plus a nonrefundable annual per-operating room fee in the amount of twenty-five dollars ($25.00)."

SECTION 34.5.(b) This section becomes effective October 1, 2003.

SECTION 34.6.(a) G.S. 131E-167(a) reads as rewritten:

"(a) Applications for certification shall be available from the Department, and each application filed with the Department shall contain all necessary and reasonable information that the Department may by rule require. A certificate shall be granted to the applicant for a period not to exceed ~~two years~~one year upon a determination by the Department that the applicant has substantially complied with the provisions of this Article and the rules promulgated by the Department under this Article. The Department shall charge the applicant a nonrefundable annual certification fee in the amount of one hundred twenty-five dollars ($125.00)."

SECTION 34.6.(b) This section becomes effective October 1, 2003.

SECTION 34.7.(a) Article 16 of Chapter 131E of the General Statutes is amended by adding the following new section to read:

"**§ 131E-269. Authorization to charge fee for certification of facilities suitable to perform abortions.**

MOST TEXT APPLIES ONLY TO THE 2003-2005 FISCAL BIENNIUM

SECTION 49.3. Except for statutory changes or other provisions that clearly indicate an intention to have effects beyond the 2003-2005 fiscal biennium, the textual provisions of this act apply only to funds appropriated for, and activities occurring during, the 2003-2005 fiscal biennium.

EFFECT OF HEADINGS

SECTION 49.4. The headings to the parts and sections of this act are a convenience to the reader and are for reference only. The headings do not expand, limit, or define the text of this act, except for effective dates referring to a Part.

SEVERABILITY CLAUSE

SECTION 49.5. If any section or provision of this act is declared unconstitutional or invalid by the courts, it does not affect the validity of this act as a whole or any part other than the part so declared to be unconstitutional or invalid.

EFFECTIVE DATE

SECTION 49.6. Except as otherwise provided, this act becomes effective July 1, 2003.

In the General Assembly read three times and ratified this the 30th day of June, 2003.

s/ Beverly E. Perdue
President of the Senate

s/ Richard T. Morgan
Speaker of the House of Representatives

s/ Michael F. Easley
Governor

Approved 5:18 p.m. this 30th day of June, 2003