

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	

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	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

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		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

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@unhealth.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.

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			<p>rehabilitation program. http://edocket.access.gpo.gov/cfr_2010/octqtr/pdf/42cfr410.49.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</p>	
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
				<p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
3) 10A NCAC 14F .1202 – Certification Process	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
4) 10A NCAC 14F .1203 – Certificate Renewal	5/17/16	4a)	Please see my comment under definitions. Debbie Scotten	<p>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</p>

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

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				<p>The referenced rule defines the licensure renewal application process which is consistent with DHSR standard operating procedures.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
5) 10A NCAC 14F .1204 – Certification Following Program Changes	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>

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6) 10A NCAC 14F .1205 – Inspections	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
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	<p>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.</p>
	5/17/16	7b)	Please see my comment under definitions. Debbie Scotten	<p>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</p>

Rule Citation & Title	Date	Commenter	Comment	Agency Response
				<p>parameters for Medicare reimbursement as opposed to regulatory oversight which exceeds the scope of DHSR.</p> <p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
9) 10A NCAC 14F .1302 – Policies and Procedures	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p>

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				<p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
10) 10A NCAC 14F .1303 – Continuous Quality Improvement	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
11) 10A NCAC 14F .1401 – Patient Rights	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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</p>

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				<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
12) 10A NCAC 14F .1501 – Admission and Discharge	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
	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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
	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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
		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.

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			<p>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?</p>	
<p>16) 10A NCAC 14F .1801 - Personnel</p>	<p>4/1/16</p>	<p>16a) Janis McLaughlin, WakeMed jamclaughlin@wakemed.org</p>	<p>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.</p>	<p>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.</p>
	<p>5/17/16</p>	<p>16b) ,</p>	<p>Please see my comment under definitions. Debbie Scotten</p>	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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				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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
19) 10A NCAC 14F .1804 – Mental Health Services	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p>

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				<p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
20) 10A NCAC 14F .1805 – Vocational Counseling and Services	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
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

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				<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
22) 10A NCAC 14F .1901 – Emergency Plan	5/17/16	22a)	Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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				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.	<p>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.</p> <p>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.</p>
23) 10A NCAC 14F .1902 – Emergency Equipment	5/17/16	23a)	Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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				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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
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

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Medical Records				<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
26) 10A NCAC 14F .2002 – Content of Medical Records	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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				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	<p>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.</p> <p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
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

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Testing Laboratory				<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
29) 10A NCAC 14F .2103 – Exercise Therapy	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an</p>

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				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	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
31) 10A NCAC 14F .2105 – Mental Health Services	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p>

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				<p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>
32) 10A NCAC 14F .2106 – Vocational Rehabilitation Services	5/17/16		Please see my comment under definitions. Debbie Scotten	<p>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.</p> <p>Comments requesting 10A NCAC 14F be deemed unnecessary would require legislative amendment to §131E-165 Cardiac Rehabilitation Certification Program.</p> <p>Comments addressing the ten year rule review process would require an amendment to § 150B- 21.3A. Periodic review and expiration of existing rules.</p>