

Fiscal Impact Analysis –Proposed Rule Change  
NC Division of Health Service Regulation  
Certificate of Need Section

Agency Division of Health Service Regulation  
Division Director

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Rule Titles 10A NCAC 14C .0102 LOCATION OF THE AGENCY  
10A NCAC 14C .0302 HEALTH MAINTENANCE ORGANIZATIONS  
10A NCAC 14C .3301 DEFINITIONS  
10A NCAC 14C .3302 INFORMATION REQUIRED OF APPLICANT  
10A NCAC 14C .3303 PERFORMANCE STANDARDS  
10A NCAC 14C .3305 STAFFING AND STAFF TRAINING

Statutory Authority: G.S. 131E-177

|                             |    |
|-----------------------------|----|
| Federal Impact              | NO |
| State Impact                | NO |
| Local Impact                | NO |
| Public/Provider Impact      | NO |
| Substantial Economic Impact | NO |

**10A NCAC 14C .0102 LOCATION OF THE AGENCY**

*Summary of the Proposed Revisions*

On June 1, 2011, the Certificate of Need (CON) Section along with the Division of Health Service Regulation Division Office vacated the Council Building on the Dorothea Dix Campus, relocating to the Edgerton Building on the Dix Campus. The Council Building’s location is 701 Barbour Drive, Raleigh, NC 27603. The Edgerton Building’s location is 809 Ruggles Drive, Raleigh, NC 27603. The Council Building is now part of the NC State University Centennial Campus. The Council Building is currently vacant.

The CON Section receives applications and written comments, as prescribed by law and by rule, by delivery service and in person by applicants or their representatives. Failure to correct the address in the rule could result in documents failing to arrive at the agency in a timely manner, causing applicants to be disqualified from competing in a review. Such an action creates a hardship on the applicant and could also result in costly litigation for the agency. It is not prudent or feasible for the agency to assign staff to wait outside the

door at the Council Building on deadline days in the event of a wayward applicant or commenter.

The proposed amendment is considered a technical change and has no economic impact on the State, local governments, or private-sector entities.

## **10A NCAC 14C .0302 HEALTH MAINTENANCE ORGANIZATIONS**

### *Summary of the Proposed Repeal*

The rule is now obsolete as the authority for this rule was repealed. The authorizing statute, G.S. 131E-180, was repealed by Session Law 2005-325, s. 2, effective August 26, 2005.

Because there no longer exists any authority to enforce Rule 10A NCAC 14C .0302, repeal of this rule will have no economic impact on the State, local governments, or private-sector entities.

## **10A NCAC 14C .3301 DEFINITIONS**

## **10A NCAC 14C .3302 INFORMATION REQUIRED OF APPLICANT**

## **10A NCAC 14C .3303 PERFORMANCE STANDARDS**

## **10A NCAC 14C .3305 STAFFING AND STAFF TRAINING**

### *Summary of the Proposed Repeals*

The Certificate of Need Law was amended in 1993 to include the regulation of air ambulances. Later in 1993, the rules codified at 10A NCAC 14C .3300 Criteria and Standards for Air Ambulance were adopted. In 2006, an out-of-state air ambulance service was denied a certificate of need to develop an air ambulance in North Carolina. It brought suit against the Certificate of Need (CON) Section in Federal Court. The suit was filed in the Eastern District of North Carolina. The court ruled, citing the Airline Deregulation Act (ADA) of 1978, that the North Carolina Certificate of Need Law was preempted from regulating an air ambulance. (*Med-Trans Corp. v. Benton*, 581 F Supp. 2d 721 [E. D. N.C. 2008]) Thus, the rules have been unenforceable since that decision, rendering the rules obsolete.

Because there no longer exists any authority to enforce these rules, their repeal will have no economic impact on the State, local governments, or private-sector entities.

## APPENDIX 1

10A NCAC 14C .0102 is proposed for amendment as follows:

### **10A NCAC 14C .0102      LOCATION OF THE AGENCY**

As used in this Subchapter, the agency is the Certificate of Need Section in the Division of Health Service Regulation, North Carolina Department of Health and Human Services. The location of the agency is ~~701 Barbour Drive~~, 809 Ruggles Drive, Raleigh, North Carolina, 27603. The mailing address of the agency is Certificate of Need Section, Division of Health Service Regulation, 2704 Mail Service Center, Raleigh, NC 27699-2704. The telephone number of the agency is 919-855-3873.

*History Note:*      *Authority G.S. 131E-177;*  
                          *Eff. November 1, 1996;*  
                          *Amended Eff. Nov. 1, 2012; January 1, 2000.*

## APPENDIX 2: Proposed Repeal

10A NCAC 14C .0302 is proposed for repeal as follows:

### **10A NCAC 14C .0302 HEALTH MAINTENANCE ORGANIZATIONS**

*History Note: Authority G.S. 131E-177; 131E-180;*  
*Eff. January 1, 1982;*  
*Amended Eff. November 1, 1996; January 1, 1990; November 1, 1989; February 1, 1986;*  
*Temporary Amendment Eff. January 1, 2000;*  
*Amended Eff. April 1, ~~2001~~ 2001;*  
*Repealed Eff. Nov. 1, 2012.*

## APPENDIX 2: Text of Rule Proposed for Repeal

### **10A NCAC 14C .0302 HEALTH MAINTENANCE ORGANIZATIONS**

- (a) Applications for an exemption under G.S. 131E-180 shall be reviewed pursuant to the review schedule in this Subchapter that is applicable for the new institutional health service for which the inpatient health service facility is requesting the exemption.
- (b) An applicant proposing to request an exemption under G.S. 131E-180 shall complete the certificate of need application form for the new institutional health service for which the exemption is requested and the supplemental form for a health maintenance organization exemption.
- (c) Applications for an exemption shall be filed and reviewed in accordance with 10A NCAC 14C .0203-.0205.
- (d) The Agency shall determine whether the applicant for the exemption is a qualified applicant as defined in G.S. 131E-180(b).
- (e) If the Agency decision is to not grant the exemption, the applicant shall not develop or offer the new institutional health service without first obtaining a certificate of need.
- (f) If a decision is made that a certificate of need is required, the review for the certificate of need shall be conducted in the same review period as for the exemption. The Agency shall determine if the application conforms with the applicable review criteria of G.S. 131E-183(a) and G.S. 131E-183(b). The Agency shall determine which plans, standards and criteria are applicable to the review of the proposal. If the proposal is not consistent with all applicable criteria in G.S. 131E-183(a), the Agency may approve or conditionally approve the proposal for a certificate of need if it conforms with the criteria set forth in G.S. 131E-180(e)(i)-(ii) and G.S. 131E-183(a)(10).

*History Note: Authority G.S. 131E-177; 131E-180;  
Eff. January 1, 1982;  
Amended Eff. November 1, 1996; January 1, 1990; November 1, 1989; February 1, 1986;  
Temporary Amendment Eff. January 1, 2000;  
Amended Eff. April 1, 2001.*

## APPENDIX 3: Rules Proposed for Repeal

10A NCAC 14C .3301 is proposed for repeal as follows:

### **SECTION .3300 - CRITERIA AND STANDARDS FOR AIR AMBULANCE**

#### **10A NCAC 14C .3301    DEFINITIONS**

*History Note:*     *Authority G.S. 131E-177(1); 131E-183(b);*  
                          *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the*  
                          *permanent rule becomes effective, whichever is sooner;*  
                          *Eff. February 1, 1994;*  
                          *Temporary Amendment Eff. May 15, 2002;*  
                          *Amended Eff. April 1, 2007; April 1, ~~2003~~ 2003;*  
                          *Repealed Eff. Nov. 1, 2012.*

10A NCAC 14C .3302 is proposed for repeal as follows:

#### **10A NCAC 14C .3302    INFORMATION REQUIRED OF APPLICANT**

*History Note:*     *Authority G.S. 131E-177(1); 131E-183(b);*  
                          *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the*  
                          *permanent rule becomes effective, whichever is sooner;*  
                          *Eff. February 1, 1994;*  
                          *Temporary Amendment Eff. May 15, 2002;*  
                          *Amended Eff. April 1, ~~2003~~ 2002;*  
                          *Repealed Eff. Nov. 1, 2012.*

10A NCAC 14C .3303 is proposed for repeal as follows:

**10A NCAC 14C .3303      PERFORMANCE STANDARDS**

*History Note:      Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the  
permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
Temporary Amendment Eff. May 15, 2002;  
Amended Eff. April 1, 2005; April 1, ~~2003~~; 2003;  
Repealed Eff. Nov. 1, 2012.*

10A NCAC 14C .3305 is proposed for repeal as follows:

**10A NCAC 14C .3305      STAFFING AND STAFF TRAINING**

*History Note:      Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the  
permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
Temporary Amendment Eff. May 15, 2002;  
Amended Eff. April 1, ~~2003~~; 2003;  
Repealed Eff. Nov. 1, 2012.*

## APPENDIX 3: Text of Rules Proposed for Repeal

### SECTION .3300 - CRITERIA AND STANDARDS FOR AIR AMBULANCE

#### 10A NCAC 14C .3301 DEFINITIONS

The following definitions shall apply to all rules in this Section:

- (1) "Air ambulance" as defined in G.S. 131E-176(1a).
- (2) "Air ambulance service" means an entity engaged in the operation of an air ambulance transporting patients.
- (3) "Air ambulance service area" means a geographic area defined by the applicant from which the project's patients originate.
- (4) "Approved air ambulance" means either a rotary air ambulance or a fixed wing air ambulance that was not operational prior to the beginning of the review period but which had been acquired prior to March 18, 1993 in accordance with 1993 N.C. Sess. Laws c.7, s. 12.
- (5) "Capacity of fixed wing air ambulance" means the maximum number of hours the aircraft can be operated as defined by the aircraft manufacturer.
- (6) "Existing air ambulance" means either a rotary air ambulance or a fixed wing air ambulance in operation prior to the beginning of the review period.
- (7) "Inter-facility patient transport" means the transport of a patient from one facility to another facility.
- (8) "Level 2 trauma center" as defined in North Carolina's Trauma Center Criteria developed by the OEMS pursuant to 10A NCAC 03D .3201(16).
- (9) "Patient" as defined in G.S. 131E-155(16).
- (10) "Scene transport" means the transport of a patient from the scene of a medical emergency.
- (11) "Base of an air ambulance service" means the site at which medical control and operation of an air ambulance is located. Unless otherwise specified, if an air ambulance service provider is a health service facility, the base of an air ambulance service is presumed to be the facility itself. Notwithstanding anything in this regulation, an air ambulance service provider may station its air ambulance at an airport within the county of its base facility or within 25 miles of its base facility.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
Temporary Amendment Eff. May 15, 2002;  
Amended Eff. April 1, 2007; April 1, 2003.*

#### 10A NCAC 14C .3302 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire an air ambulance shall use the Acute Care Facility/Medical Equipment Application Form.

(b) The applicant shall also provide the following additional information:

- (1) the number of air ambulance aircraft by type and make currently operated and to be operated in the "air ambulance" service area following completion of the proposed project;
- (2) if the applicant is a current air ambulance service provider, documentation of the applicant's experience in transporting patients via air ambulance during the past 12 months, including:
  - (A) the number of scene transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing); and
  - (B) the number of inter-facility patient transports by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing);



- (3) if the applicant is a health service facility proposing to establish a new air ambulance service, the applicant shall provide documentation of:
  - (A) the number of scene transports to their facility by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) during the past 12 months; and
  - (B) the number of inter-facility patient transports during the past 12 months by air ambulance by type of air ambulance (i.e., fixed wing and rotary wing) to their facility from other facilities and from their facility to other facilities;
- (4) the number of patients from the proposed air ambulance service area that are projected to require air ambulance service by type of aircraft and the patients' county of residence and county from which transported in each of the first 12 calendar quarters of operation following completion of the project, including the methodology and assumptions used for the projections;
- (5) the projected utilization of the air ambulance service per aircraft for each of the first 12 calendar quarters following completion of the proposed project by type of patient (e.g., neonatal, pediatric, cardiac), including the methodology and assumptions used for these projections;
- (6) documentation which demonstrates that existing air ambulance services in the State are unable to accommodate the applicant's projected need for an additional air ambulance;
- (7) as appropriate to the type of aircraft proposed, documentation of referral sources for air ambulance patients and evidence of the willingness of hospitals to participate;
- (8) documentation which demonstrates the applicant's capability to communicate with and access emergency transportation resources including, but not limited to ground mobile intensive care ambulance services;
- (9) evidence of the applicant's capability to provide air ambulance services on a 24 hour per day, seven day per week basis except as precluded by weather, maintenance and other factors as applicable;
- (10) documentation of in service training or continuing education programs for staff;
- (11) documentation of written policies and procedures for the operation of the air ambulance service, which shall be in effect at the time the proposed air ambulance becomes operational, for at least the following:
  - (A) alternative arrangements for transport of a patient when patient transport cannot be provided by the applicant; e.g. a current Mutual Aid Agreement with one or more permitted air ambulance services;
  - (B) written criteria for patient transport;
  - (C) medical crew contact with medical control;
  - (D) operation of an audit and review panel;
  - (E) patient treatment protocols;
  - (F) patient transfer protocols;
  - (G) communication, including incoming calls, dispatch, and on-going communication with air ambulance flight and medical crew and other emergency medical service providers;
  - (H) role in disaster plans;
  - (I) coordination with local emergency medical service systems in the proposed air ambulance service area or other providers as appropriate given the type of aircraft and service proposed;
- (12) if the applicant is an existing air ambulance service provider, copies of the following, as applicable:
  - (A) the current permit(s) issued by the OEMS and evidence that the permit(s) has not been denied or revoked,
  - (B) the current FAA Part 135 or Part 91 Certificate, and
  - (C) the current FCC radio license;
- (13) if an applicant does not currently operate an air ambulance, evidence that the OEMS, FCC and FAA are aware of the proposed air ambulance and that the applicant expects to be able to obtain all required permits, licenses or certifications;
- (14) documentation of the aircraft selection analysis used by the applicant and reason for selection of the aircraft proposed;

- (15) documentation of a financial analysis of a lease versus purchase option for acquisition of the proposed aircraft and the method (e.g., hire own versus contract) of providing personnel to fly the aircraft and the reason for selection of the option proposed; and
- (16) if the applicant proposes the acquisition of a fixed wing air ambulance, documentation of the capacity of each existing fixed wing air ambulance based in the state.

*History Note: Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the  
permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
Temporary Amendment Eff. May 15, 2002;  
Amended Eff. April 1, 2003.*

### **10A NCAC 14C .3303 PERFORMANCE STANDARDS**

An applicant proposing to acquire an air ambulance shall demonstrate that the project meets the following standards:

- (1) For the acquisition of a rotary air ambulance [unless 10A NCAC 14C .3303(6) is applicable or unless the applicant is proposing to acquire an air ambulance that will be based at a site that is 75 air miles or more from the base of another air ambulance service], each rotary air ambulance proposed to be acquired by the applicant shall be utilized at an average rate of at least 60 patient requests per month, measured during the fourth quarter of the second year following completion of the project (the applicant shall document the assumptions and provide data supporting the methodology used for the projections).
- (2) For the acquisition of a rotary air ambulance [unless 10A NCAC 14C .3303(6) is applicable], an applicant proposing to add a rotary air ambulance to an existing rotary air ambulance service shall demonstrate that all of its existing rotary air ambulances have had at least 60 patient requests per month in the last year.
- (3) For the acquisition of a fixed wing air ambulance [unless 10A NCAC 14C .3303(6) is applicable or unless the applicant is proposing to acquire an air ambulance that will be based at a site that is 75 air miles or more from the base of another air ambulance service], each fixed wing air ambulance proposed to be acquired by the applicant shall be utilized at an average of no less than 60% of capacity transporting patients (determined based on the type aircraft), measured during the fourth quarter of the second year following completion of the project (the applicant shall document the assumptions and provide data supporting the methodology used for the projections).
- (4) For the acquisition of a fixed wing air ambulance [unless 10A NCAC 14C .3303(6) is applicable], an applicant proposing to add a fixed wing air ambulance to an existing fixed wing air ambulance service shall demonstrate that all of its existing fixed wing air ambulances have been utilized at no less than 60% of capacity transporting patients for the last year.
- (5) For all proposed projects involving the development of a new air ambulance service (rotary or fixed wing), the new service shall be developed with either a Level I trauma center as designated by the North Carolina Office of Emergency Medical Services pursuant to 10A NCAC 13P .0901 or .0902 that reported more than 1500 trauma patients to the North Carolina Trauma Registry during the most recent 12 month reporting period; or a Level I or Level II trauma center as designated by the North Carolina Office of Emergency Medical Services pursuant to 10A NCAC 13P .0901 or .0902 that shall not be based within 60 miles of the base of an existing air ambulance service.
- (6) For acquisition of an air ambulance that shall be utilized less than 25 percent of the time flown for purposes defined in G.S. 131E-176(1a), the applicant shall provide the following information:
  - (a) documentation that the aircraft shall be utilized less than 25 percent of the time flown in any given quarter for purposes defined in G.S. 131E-176(1a) (the applicant shall document the assumptions and provide data supporting the methodology used for the projections); and

- (b) a detailed description of all circumstances and conditions under which the aircraft will be utilized including the number of hours the aircraft will be flown for each of these circumstances.

*History Note:* Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
Temporary Amendment Eff. May 15, 2002;  
Amended Eff. April 1, 2005; April 1, 2003.

**10A NCAC 14C .3304 RESERVED FOR FUTURE CODIFICATION**

**10A NCAC 14C .3305 STAFFING AND STAFF TRAINING**

(a) The applicant shall demonstrate that the following staff shall be available to provide air ambulance services:

- (1) if applicable, personnel available as needed for transport of special care patients (e.g., neonatal, cardiac); and
- (2) personnel that are trained to operate the ground communication network.

(b) The applicant shall provide an organized program of staff education and training which is integral to the air ambulance service and ensures improvements in technique and the proper training of personnel.

*History Note:* Authority G.S. 131E-177(1); 131E-183(b);  
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;  
Eff. February 1, 1994;  
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