

**OSBM Review 2011-08-11
Not a Significant Rule Change**

**Division of Health Service
Regulation**

Agency Proposing Rule Change:

Introductory Note: These rules were presented to the Medical Care Commission and stakeholders on May 5 and 13, 2011 to receive input and initiate rule-making without any objections.

	Title of Rule Change	Statutory Citation	Summary of the Rule Change	Projected Fiscal Impact on Federal, State, and Local Governments, and on Providers
1	Application Requirements, .2101	G.S. 131E-104	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. Number "(5) accreditation data;" was struck because there is no requirement for that criteria. G.S. 131E-102, Licensure requirements, was added as an appropriate authority for the rule. This rule was effective January 1, 1996 and has had no amendments since that time.	None
2	Public Access to Department Licensure Records, .2110	G.S. 8-53; 108A-80; 131E-104; 131E-124(c); 132-1.1	Repeal. Compliance is achieved via the Public Records Law N.C.G.S. Chapter 132	None
3	Infection Control, .2209	131E-104; 131E-113	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. Language has been simplified and clarified. References have been updated. G.S. 131E-113, Immunizations of employees and residents, was added as an appropriate authority for the rule. This rule was effective January 1, 1996 and has had no amendments since that time.	None
4	Nurse Aides, .2304	131E-104; 131E-255; 143B-165; 42 U.S.C. 1395; 42 U.S.C. 1396	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. The price was removed and the web address was added. G.S. 131E-111 was removed as an authority because it was recodified and 131E-	None

			255 was added. This rule was effective January 1, 1996 and has had no amendments since that time.	
5	Adult Care Home Personnel Requirements, .2308	131E-104; 131E-255; 143B-165; 42 U.S.C. 1395; 42 U.S.C. 1396	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. Part c was removed from the rule because it contradicts rule 10A NCAC 13D .2104. G.S. 131E-111 was removed as an authority because it was recodified and 131E-255 was added. This rule was effective January 1, 1996 and has had no amendments since that time.	None
6	Drug Storage and Disposition, .2605	131E-104; 131E-117	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. References were corrected and a web address was added. This rule was effective January 1, 1996 and has had no amendments since that time.	None
7	Pharmaceutical Records, .2606	131E-104; 131E-117	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. References were corrected and a web address was added. This rule was effective January 1, 1996 and has had no amendments since that time.	None
8	Emergency Drugs, .2607	131E-104; 131E-117	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. References were corrected and a web address was added. This rule was effective January 1, 1996 and has had no amendments since that time.	None

9	Provision of Nutrition and Dietetic Services, .2701	131E-104; 90-368(4)	The proposed amendment makes language more consistent with previous recommendations from the Rules Review Commission. References were corrected and a web address was added. This rule was effective January 1, 1996 and has had no amendments since that time. A new appropriate authority was added.	None
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1 **APPENDIX**

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4 10A NCAC 13D .2101 is proposed for adoption as follows:

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6 **10A NCAC 13D .2101 APPLICATION REQUIREMENTS**

7 (a) ~~An~~ A legal entity shall submit an application for licensure for a new facility ~~shall be submitted~~ to the Nursing Home
8 Licensure and Certification Section of the Division of Health Service Regulation at least 30 days prior to a license being issued
9 or patients admitted.

10 (b) The application shall contain the following:

- 11 (1) legal identity of applicant (licensee) and mailing address;
- 12 (2) name or names under which the facility is presented to the public;
- 13 (3) location and mailing address of facility;
- 14 (4) ownership disclosure;
- 15 ~~(5) accreditation data;~~
- 16 ~~(6)~~ (5) bed complement;
- 17 ~~(7)~~ (6) magnitude and scope of services offered;
- 18 ~~(8)~~ (7) name and current license number of the administrator; ~~and~~
- 19 ~~(9)~~ (8) name and current license number of the director of ~~nursing~~; nursing; ~~and~~
- 20 (9) name and current license number of the medical director.

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22 *History Note: Authority G.S. 131E-104; 131E-102;*

23 *Eff. January 1, ~~1996~~; 1996;*

24 *Amended Eff. July 1, 2012.*

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1 10A NCAC 13D .2110 is proposed for repeal as follows:

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10A NCAC 13D .2110 PUBLIC ACCESS TO DEPARTMENT LICENSURE RECORDS

History Note: Authority G.S. 8-53; 108A-80; 131E-104; 131E-124(c); 132-1.1;
Eff. January 1, ~~1996~~ 1996;
Repealed Eff. July 1, 2012.

1 10A NCAC 13D .2209 is proposed for adoption as follows:

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10A NCAC 13D .2209 INFECTION CONTROL

(a) ~~The~~ A facility shall establish and maintain an infection control program for the purpose of providing a safe, clean and comfortable environment and preventing the transmission of diseases and infection.

(b) Under the infection control program, the facility shall decide what procedures, such as isolation techniques, are needed for individual patients, investigate episodes of infection and attempt to control and prevent infections in the facility.

(c) The facility shall maintain records of infections and of the corrective actions taken.

(d) ~~The facility shall ensure communicable disease screening, testing including tuberculosis, as required by 10A NCAC 41A, "Communicable Disease Control" which is incorporated by reference, including subsequent amendments. Copies of these Rules may be obtained at no charge by contacting the N.C. Department of Health and Human Services, Division of Public Health, Tuberculosis Control Branch, 1902 Mail Service Center, Raleigh, North Carolina 27699-1902. Screening shall be done upon prior to admission of all patients being admitted from settings other than hospitals, nursing facilities or combination facilities; facilities. prior to or upon admission for all patients admitted from hospitals, nursing facilities and combination facilities; and Staff shall be screened within seven days upon the hiring of all staff. of the hire date. The facility shall ensure tuberculosis screening annually thereafter for patients and staff staff, as required by 10A NCAC 41A, "Communicable Disease Control" which is incorporated by reference, including subsequent amendments. Copies of these Rules may be obtained at no charge by contacting the N.C. Department of Health and Human Services, Division of Public Health, Tuberculosis Control Branch, 1902 Mail Service Center, Raleigh, North Carolina 27699-1902. Identification of a communicable disease does not, in all cases, in and of itself, preclude admission to the facility.~~

(e) All cases of reportable disease as defined by 10A NCAC 41A "Communicable Disease Control" and ~~epidemic outbreaks, and poisonings outbreaks consisting of two or more linked cases of disease transmission~~ shall be reported immediately to the local health department.

(f) The facility shall ~~isolate~~ use isolation precautions for any patient deemed appropriate by the its infection control program. program and as recommended by the following Centers for Disease Control guidelines, Management of Multidrug-Resistant Organisms In Healthcare Settings, 2006, <http://www.cdc.gov/ncidod/dhqp/pdf/ar/MDROGuideline2006.pdf> and 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, <http://www.cdc.gov/hicpac/2007ip/2007isolationprecautions.html>.

(g) The facility shall prohibit any employee with a communicable disease or infected skin lesion from direct contact with patients or their food, if direct contact is the mode of transmission of the disease.

(h) The facility shall require all staff to use good hand washing technique as indicated in the Centers for Disease ~~Control and Prevention~~ "Guidelines for Hand Washing in Hospital Environmental Control," as published by the U.S. Department of Health and Human Services, Public Health Service which is incorporated by reference, including subsequent amendments. Copies may be purchased from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, Virginia, 22161 for fifteen dollars and 95 cents (\$15.95). Control, "Guideline for Hand Hygiene in Health-Care Settings, Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force". This information can be accessed at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>.

(i) All linen shall be handled, store, processed and transported so as to prevent the spread of infection.

1 *History Note:* *Authority G.S. 131E-104; 131E-113*
2 *Eff. January 1, ~~1996~~; 1996;*
3 *Amended Eff. July 1, 2012.*

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1 10A NCAC 13D .2304 is proposed for adoption as follows:

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10A NCAC 13D .2304 NURSE AIDES

(a) ~~The~~ A facility shall employ or contract individuals as nurse aides in compliance with N.C. General Statute 131E, Article 15 and facilities certified for Medicare or Medicaid participation shall also comply with 42 CFR Part 483 which is incorporated by reference, including subsequent amendments. ~~Copies of the~~ The Code of Federal Regulations may be ~~purchased from the~~ Superintendent of Documents, U.S. Government Printing Office, P.O. Box 371954, Pittsburgh, PA 15202-7954 for thirty eight dollars (\$38.00) and may be purchased with a credit card by a direct telephone call to the G.P.O. at (202) 512-1800. accessed at http://www.access.gpo.gov/nara/cfr/waisidx_08/42cfr483_08.

(b) ~~The~~ A facility shall provide to the Department, upon request, verification of in-service training and of past or present employment of any nurse aide employed by the facility.

History Note: Authority G.S. 131E-104; ~~131E-111~~; 131E-255; 143B-165; 42 U.S.C. 1395; 42 U.S.C. 1396; Eff. January 1, ~~1996~~; 1996; Amended Eff. July 1, 2012.

1 10A NCAC 13D .2308 is proposed for adoption as follows:

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10A NCAC 13D .2308 ADULT CARE HOME PERSONNEL REQUIREMENTS

(a) The administrator of a combination home shall designate a person to be in charge of the adult care home residents at all times. The nurse-in-charge of the nursing facility may also serve as supervisor-in-charge of the domiciliary beds.

(b) If adult care home beds are located in a separate building or a separate level of the same building, there shall be a person on duty in the adult care home portion of the facility at all times.

~~(c) The facility shall comply with all rules in Subchapter 10A NCAC 13F, Licensing of Homes for the Aged and Infirm, which is incorporated by reference, including all subsequent amendments. Copies of these Rules can be obtained free of charge from the Division of Health Service Regulation, Adult Care Licensure Section, 2708 Mail Service Center, Raleigh, NC 27699 2708.~~

*History Note: Authority G.S. 131E-104;
Eff. January 1, 1996. 1996;
Amended Eff. July 1, 2012.*

1 10A NCAC 13D .2605 is proposed for adoption as follows:

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3 **10A NCAC 13D .2605 DRUG STORAGE AND DISPOSITION**

4 (a) ~~The pharmacist and director of nursing~~ A facility shall ensure that drug storage areas are clean, secure, well lighted and
5 well ventilated; that room temperature is maintained between 59 degrees F. and 86 degrees F.; and that the following
6 conditions are met:

7 (1) All drugs shall be maintained under locked security except when under the ~~immediate or~~ direct physical
8 supervision of a nurse or pharmacist.

9 (2) Drugs requiring refrigeration shall be stored in a refrigerator containing a thermometer and capable of
10 maintaining a temperature range of 2 degrees C. to 8 degrees C. (36 degrees F. to 46 degrees F.) Drugs shall
11 not be stored in a refrigerator containing non-drugs and non-drug related items, except when stored in a
12 separate container.

13 (3) Drugs intended for topical use, except for ophthalmic, otic and transdermal medications, shall be stored in a
14 ~~designated an~~ area separate from the drugs intended for oral and injectable use.

15 (4) Drugs that are outdated, discontinued or deteriorated shall be removed from the facility within five days.

16 (b) Upon discontinuation of a drug or upon discharge of a patient, the remainder of the drug supply shall be disposed of
17 ~~promptly.~~ according to the facility's policy. If it is reasonably expected that the patient ~~shall~~ will return to the facility and that
18 the drug therapy will be resumed, the remaining drug supply may be held for not more than 30 calendar days after the date of
19 discharge or discontinuation.

20 (c) The disposition of drugs shall be in accordance with written policies and procedures established by the Quality Assurance
21 Committee.

22 (d) Destruction of controlled substances shall be in compliance with Disposal of Unused Controlled Substances From Nursing
23 Home as described in North Carolina Controlled Substance Act and Regulations (10A NCAC 26E .0406) 10A NCAC 26E
24 .0406, which is hereby incorporated by reference including subsequent amendments. ~~Copies of the rules may be obtained from~~
25 ~~the Drug Regulatory Branch, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3016 Mail~~
26 ~~Service Center, Raleigh, NC 27699 3016 at a cost of thirteen dollars (\$13.00).~~ These rules can be accessed online at
27 <http://reports.oah.state.nc.us/ncac.asp>.

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29 *History Note: Authority G.S. 131E-104; 131E-117;*
30 *RRC objection due to lack of statutory authority Eff. July 13, 1995;*
31 *Eff. January 1, ~~1996.~~ 1996;*
32 *Amended Eff. July 1, 2012.*
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1 10A NCAC 13D .2606 is proposed for adoption as follows:

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10A NCAC 13D .2606 PHARMACEUTICAL RECORDS

(a) ~~The pharmacist~~ A facility shall ensure that accurate records of the receipt, use and disposition of drugs are maintained and readily available.

(b) ~~The director of nursing and pharmacist~~ A facility shall ensure accountability of controlled substances as defined by the Disposal of Unused Controlled Substances From Nursing Home as described in North Carolina Controlled Substance Act and Regulations (10A NCAC 26E .0406) 10A NCAC 26E .0406, which is hereby incorporated by reference including subsequent amendments. ~~Copies of the rules may be obtained from the Drug Regulatory Branch, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3016 Mail Service Center, Raleigh, NC 27699-3016 at a cost of thirteen dollars (\$13.00). These rules can be accessed online at <http://reports.oah.state.nc.us/ncac.asp>.~~

History Note: Authority G.S. 131E-104; 131E-117;
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, ~~1996~~; 1996;
Amended Eff. July 1, 2012.

1 10A NCAC 13D .2607 is proposed for adoption as follows:

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10A NCAC 13D .2607 EMERGENCY DRUGS

(a) ~~The~~ A facility shall maintain a supply of emergency drugs in compliance with ~~21 NCAC 46 .1403~~ 10A NCAC 26E .0408 which is hereby incorporated by reference including subsequent amendments. ~~Copies of the rule may be obtained from the North Carolina Board of Pharmacy, P.O. Box 459, Carrboro Plaza, Highway 54 Bypass, Carrboro, North Carolina 27510 at a cost of eight dollars and forty eight cents (\$8.48). This rule can be accessed online at <http://reports.oah.state.nc.us/ncac.asp>.~~

(b) Emergency drugs shall be stored in a portable container sealed with an easily breakable closure which cannot be resealed or reused and shall be readily accessible for use.

(c) Emergency drug kits shall be stored in a ~~secure area~~ locked storage cabinet or room out of ~~site~~ sight of patients and the general public. If stored in a locked area the kits shall be ~~immediately~~ accessible to all licensed nursing personnel.

(d) All emergency drugs and quantity to be maintained shall be approved by the Quality Assurance ~~Committee~~. Committee as defined in 10A NCAC 13D .2212.

(e) If emergency drug items require refrigerated storage, they shall be stored in a separate sealed container within the medication refrigerator. The container shall be labeled to indicate the emergency status of the enclosed drug and sealed as indicated in Paragraph (b) of this Rule.

(f) An accurate inventory of emergency drugs and supplies shall be maintained with each emergency drug kit.

(g) ~~The pharmacist~~ A facility shall ~~personally~~ examine the refrigerated and non-refrigerated emergency drug supply at least every 90 days and make any necessary changes at that time.

(h) The facility shall have written policies and procedures which are enforced to ensure that in the event the sealed emergency drug container is opened and contents utilized, ~~immediate~~ steps are taken to replace the items used.

(i) The availability of a controlled substance in an emergency kit shall be in compliance with the North Carolina Controlled Substances Act and Regulations (10A NCAC 26E) which is hereby incorporated by reference including subsequent amendments. ~~Copies of the rules may be obtained from the Drug Regulatory Branch, Division of Mental Health, Developmental Disabilities and Substance Abuse Services, 3016 Mail Service Center, Raleigh, NC 27699-3016 at a cost of thirteen dollars (\$13.00). These rules can be accessed online at <http://reports.oah.state.nc.us/ncac.asp>.~~

History Note: Authority G.S. 131E-104; 131E-117;
RRC objection due to lack of statutory authority Eff. July 13, 1995;
Eff. January 1, ~~1996~~; 1996;
Amended Eff. July 1, 2012.

1 10A NCAC 13D .2701 is proposed for adoption as follows:

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10A NCAC 13D .2701 PROVISION OF NUTRITION AND DIETETIC SERVICES

(a) ~~The~~ A facility shall ensure that each patient is provided with a palatable diet that meets his or her daily nutritional and specialized nutritional needs.

(b) The facility shall designate a person to be known as the director of food service who shall be responsible for the facility's dietetic service and for supervision of dietetic service personnel. ~~If this person is not a dietitian, licensed dietitian/nutritionist or a registered dietitian with the Commission on Dietetic Registration, he or she shall meet the criteria for membership in the Dietary Managers Association which is hereby incorporated by reference including subsequent amendments and editions. Copies of criteria may be obtained from the Dietary Managers Association, 406 SurrySurrey Woods Drive, St. Charles , IL 60174 at no cost. or it can be accessed online at www.DMAonline.org. If the course has not been completed, this person shall be enrolled in a course and making satisfactory progress for completion within the time limit specified by course requirements.~~ a Certified Dietary Manager who is certified by the Certifying Board of the Dietary Managers, Dietetic Technician Registered, who is registered by the Commission on Dietetic Registration of the American Dietetic Association, or an individual who has met the academic requirements as referenced in G.S. 90-357(3)b.1., c.1. and d., then the person shall enroll in a course of study to obtain these qualifications and make satisfactory progress for completion within the time limit specified by course requirements.

(c) If the food service supervisor is not a dietitian, the facility shall employ a licensed dietitian/nutritionist ~~dietitian~~ on at least a consultant basis. The consultant shall submit written reports of clinical and food service operation recommendations to the administrator and food service supervisor.

(d) The dietitian shall spend sufficient time in the facility to assure the following parameters of nutrition have been addressed and that recommended successful interventions by the facility have been met:

- (1) An analysis of weight loss or gain;
- (2) Laboratory values;
- (3) Clinical indicators of malnutrition;
- (4) Drug therapy that may contribute to nutritional deficiencies;
- (5) The amount of meal and supplement consumed to meet nutritional needs;
- (6) Increased nutritional needs related to disease state or deterioration in physical or mental status, i.e., decubitus, low protein status, inadequate intake, or nutrition provided via enteral or parenteral route.

(e) There shall be sufficient dietetic personnel employed ~~competent~~ to meet the nutritional needs of all patients in the areas of therapeutic diets, food preparation and service, principles of sanitation, and resident's rights as related to food services.

(f) The facility shall ensure that menus are followed which meet the nutritional needs of patients in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences which are incorporated by reference, including subsequent amendments. Copies of this publication ~~can~~ may be obtained by contacting The National Academy Press, ~~2101 Constitution Avenue N.W., Lockbox 285, Washington, D.C., 20055.~~ 500 Fifth St. N.W., Washington, D.C. 20001 or accessing it at http://www.nap.edu/catalog.php?record_id=1349. ~~Cost of this publication is eighteen dollars and ninety five cents (\$18.95) and includes shipping and handling.~~ Menus shall:

- (1) be planned at least 14 days in advance,
- (2) provide for substitutes of similar nutritive value for patients who refuse food that is served, and

1 (3) be provided to patients orally or written through such methods as ~~posting, posting and daily announcements,~~
2 ~~periodic newsletters, etc.~~ announcements.

3 (g) Food must be prepared to conserve its nutritive value and appearance.

4 (h) Food shall be served at the preferred temperature as discerned by the resident and customary practice, in a form to meet the
5 patient's individual needs and with assistive devices as dictated by the patient's needs. Hot foods shall leave the kitchen (or
6 steam table) above ~~140~~ 135 degrees F; and cold foods below 41 degrees F; ~~E. and freezer temperatures at 0 degrees F or~~
7 ~~below.~~ The freezer must keep frozen foods frozen solid.

8 (i) If patients require assistance in eating, food shall be maintained at the appropriate temperature until assistance is provided.

9 (j) All diets, including enteral and parenteral nutrition therapy, shall be as ordered by the physician or other legally authorized
10 person, and served as ordered.

11 (k) At least three meals shall be served daily to all patients in accordance with medical orders.

12 (l) No more than 14 hours shall elapse between an evening meal containing a protein food and a morning meal containing a
13 protein food.

14 (m) Hour-of-sleep (hs) nourishment shall be available to patients upon request or in accordance with nutritional plans.

15 (n) Between meal fluids for hydration shall be available and offered to all patients in accordance with medical orders.

16 (o) The facility shall have a current online or hard copy nutrition care manual or handbook approved by the dietitian, medical
17 staff and the Administrator which shall be used in the planning of the regular and therapeutic diets and be accessible to all staff.

18 (p) Food services shall comply with Rules Governing the Sanitation of Restaurants and Other Foodhandling Establishments
19 (15A NCAC 18A .1300) as promulgated by the Commission for Public Health which ~~is~~ are incorporated by reference,
20 including subsequent amendments, assuring storage, preparation, and serving of food under sanitary conditions. Copies of
21 these Rules can be ~~obtained, at no charge, by contacting the N.C. Department of Environment and Natural Resources, Division~~
22 ~~of Environmental Health Services, 1630 Mail Service Center, Raleigh, NC 27699-1630.~~ accessed online at
23 <http://www.deh.enr.state.nc.us/rules.htm>.

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25 *History Note: Authority G.S. 131E-104; 90-368(4)*

26 *RRC objection due to lack of statutory authority Eff. July 13, 1995;*

27 *Eff. January 1, ~~1996.~~ 1996.*

28 *Amended Eff. July 1, 2012.*

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