NORTH CAROLINA

REGISTER

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Office of Administrative Hearings Rules Division 424 North Blount Street (27601) 6714 Mail Service Center Raleigh, NC 27699-6714 (919) 733-2678 FAX (919) 733-3462

For the CUMULATIVE INDEX to the NC Register go to:

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Julian Mann III, Director Camille Winston, Deputy Director Molly Masich, Director of APA Services Linda Dupree, Editorial Assistant Dana Sholes, Editorial Assistant Julie Brincefield, Editorial Assistant

NORTH CAROLINA ADMINISTRATIVE CODE CLASSIFICATION SYSTEM

The North Carolina Administrative Code (NCAC) has four major classifications of rules. Three of these, titles, chapters, and sections are mandatory. The major classification of the NCAC is the title. Each major department in the North Carolina executive branch of government has been assigned a title number. Titles are further broken down into chapters which shall be numerical in order. Subchapters are optional classifications to be used by agencies when appropriate.

NCAC TITLES		TITLE 21 LICENSING BOARDS		TITLE 24 INDEPENDENT AGENCIES	
1	ADMINISTRATION	1	Acupuncture	1 Housing Finance	
2	AGRICULTURE & CONSUMER SERVICES	2	Architecture	2 Agricultural Finance Authority	
3	AUDITOR	3	Athletic Trainer Examiners	3 Safety & Health Review	
4	COMMERCE	4	Auctioneers	Board	
5	CORRECTION	6	Barber Examiners	4 Reserved	
6	COUNCIL OF STATE	8	Certified Public Accountant Examiners	5 State Health Plan Purchasing	
7	CULTURAL RESOURCES	10	Chiropractic Examiners	Alliance Board	
8	ELECTIONS	11	Employee Assistance Professionals		
9	GOVERNOR	12	General Contractors		
10A	HEALTH AND HUMAN SERVICES	14	Cosmetic Art Examiners		
11	INSURANCE	16	Dental Examiners		
12	JUSTICE	17	Dietetics/Nutrition		
13	LABOR	18	Electrical Contractors		
14A	CRIME CONTROL & PUBLIC SAFETY	19 20	Electrolysis		
15A	ENVIRONMENT &NATURAL RESOURCES	20	Foresters Geologists		
16	PUBLIC EDUCATION	22	Hearing Aid Dealers and Fitters		
17	REVENUE	25	Interpreter/Transliterator (Reserved)		
18	SECRETARY OF STATE	26	Landscape Architects		
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		52	Professional Counselors		
		54	Psychology		
		56	Professional Engineers & Land Surveyors		
		57	Real Estate Appraisal		
		58	Real Estate Commission		
		60	Refrigeration Examiners		
		61	Respiratory Care		
		62	Sanitarian Examiners		
		63	Social Work Certification		
		64	Speech & Language Pathologists &		
			Audiologists		
		65	Therapeutic Recreation Certification		
		66	Veterinary Medical		
		68	Substance Abuse Professionals		
		69	Soil Scientists		

Note: Title 21 contains the chapters of the various occupational licensing boards and Title 24 contains the chapters of independent agencies.

NORTH CAROLINA REGISTER

Publication Schedule for January 2004 – December 2004

FILING DEADLINES		NOTICE OF TEXT		PERMANENT RULE			TEMPORARY RULES	
Volume & issue number	Issue date	Last day for filing	Earliest date for public hearing	End of required comment period	Deadline to submit to RRC for review at next meeting	Earliest Eff. Date of Permanent Rule	Delayed Eff. Date of Permanent Rule (first legislative day of the next regular session)	270 th day from publication in the Register
18:13	01/02/04	12/08/03	01/17/04	03/02/04	03/22/04	05/01/04	05/10/04	09/28/04
18:14	01/15/04	12/19/03	01/30/04	03/15/04	03/22/04	05/01/04	05/10/04	10/11/04
18:15	02/02/04	01/09/04	02/17/04	04/02/04	04/20/04	06/01/04	01/26/05	10/29/04
18:16	02/16/04	01/26/04	03/02/04	04/16/04	04/20/04	06/01/04	01/26/05	11/12/04
18:17	03/01/04	02/09/04	03/16/04	04/30/04	05/20/04	07/01/04	01/26/05	11/26/04
18:18	03/15/04	02/23/04	03/30/04	05/14/04	05/20/04	07/01/04	01/26/05	12/10/04
18:19	04/01/04	03/11/04	04/16/04	06/01/04	06/21/04	08/01/04	01/26/05	12/27/04
18:20	04/15/04	03/24/04	04/30/04	06/14/04	06/21/04	08/01/04	01/26/05	01/10/05
18:21	05/03/04	04/12/04	05/18/04	07/02/04	07/20/04	09/01/04	01/26/05	01/28/05
18:22	05/17/04	04/26/04	06/01/04	07/16/04	07/20/04	09/01/04	01/26/05	02/11/05
18:23	06/01/04	05/10/04	06/16/04	08/02/04	08/20/04	10/01/04	01/26/05	02/26/05
18:24	06/15/04	05/24/04	06/30/04	08/16/04	08/20/04	10/01/04	01/26/05	03/12/05
19:01	07/01/04	06/10/04	07/16/04	08/30/04	09/20/04	11/01/04	01/26/05	03/28/05
19:02	07/15/04	06/23/04	07/30/04	09/13/04	09/20/04	11/01/04	01/26/05	04/11/05
19:03	08/02/04	07/12/04	08/17/04	10/01/04	10/20/04	12/01/04	01/26/05	04/29/05
19:04	08/16/04	07/26/04	08/31/04	10/15/04	10/20/04	12/01/04	01/26/05	05/13/05
19:05	09/01/04	08/11/04	09/16/04	11/01/04	11/22/04	01/01/05	01/26/05	05/29/05
19:06	09/15/04	08/24/04	09/30/04	11/15/04	11/22/04	01/01/05	01/26/05	06/12/05
19:07	10/01/04	09/10/24	10/16/04	11/30/04	12/20/04	02/01/05	05/00/06	06/28/05
19:08	10/15/04	09/24/04	10/30/04	12/14/04	12/20/04	02/01/05	05/00/06	07/12/05
19:09	11/01/04	10/11/04	11/16/04	12/31/04	01/20/05	03/01/05	05/00/06	07/29/05
19:10	11/15/04	10/22//04	11/30/04	01/14/05	01/20/05	03/01/05	05/00/06	08/12/05
19:11	12/01/04	11/05/04	12/16/04	01/31/05	02/21/05	04/01/05	05/00/06	08/28/05
19:12	12/15/04	11/22/04	12/30/04	02/14/05	02/21/05	04/01/05	05/00/06	09/11/05

EXPLANATION OF THE PUBLICATION SCHEDULE

This Publication Schedule is prepared by the Office of Administrative Hearings as a public service and the computation of time periods are not to be deemed binding or controlling. Time is computed according to 26 NCAC 2C .0302 and the Rules of Civil Procedure, Rule 6.

GENERAL

The North Carolina Register shall be published twice a month and contains the following information submitted for publication by a state agency:

- (1) temporary rules;
- (2) notices of rule-making proceedings;
- (3) text of proposed rules;
- (4) text of permanent rules approved by the Rules Review Commission;
- (5) notices of receipt of a petition for municipal incorporation, as required by G.S. 120-165;
- (6) Executive Orders of the Governor;
- (7) final decision letters from the U.S. Attorney General concerning changes in laws affecting voting in a jurisdiction subject of Section 5 of the Voting Rights Act of 1965, as required by G.S. 120-30.9H;
- (8) orders of the Tax Review Board issued under G.S. 105-241.2; and
- (9) other information the Codifier of Rules determines to be helpful to the public.

COMPUTING TIME: In computing time in the schedule, the day of publication of the North Carolina Register is not included. The last day of the period so computed is included, unless it is a Saturday, Sunday, or State holiday, in which event the period runs until the preceding day which is not a Saturday, Sunday, or State holiday.

FILING DEADLINES

ISSUE DATE: The Register is published on the first and fifteen of each month if the first or fifteenth of the month is not a Saturday, Sunday, or State holiday for employees mandated by the State Personnel Commission. If the first or fifteenth of any month is a Saturday, Sunday, or a holiday for State employees, the North Carolina Register issue for that day will be published on the day of that month after the first or fifteenth that is not a Saturday, Sunday, or holiday for State employees.

LAST DAY FOR FILING: The last day for filing for any issue is 15 days before the issue date excluding Saturdays, Sundays, and holidays for State employees.

NOTICE OF TEXT

EARLIEST DATE FOR PUBLIC HEARING: The hearing date shall be at least 15 days after the date a notice of the hearing is published.

END OF REQUIRED COMMENT PERIOD An agency shall accept comments on the text of a proposed rule for at least 60 days after the text is published or until the date of any public hearings held on the proposed rule, whichever is longer.

DEADLINE TO SUBMIT TO THE RULES REVIEW COMMISSION: The Commission shall review a rule submitted to it on or before the twentieth of a month by the last day of the next month.

FIRST LEGISLATIVE DAY OF THE NEXT REGULAR SESSION OF THE GENERAL ASSEMBLY: This date is the first legislative day of the next regular session of the General Assembly following approval of the rule by the Rules Review Commission. See G.S. 150B-21.3, Effective date of rules.

IN ADDITION

Note from the Codifier: This Section contains public notices that are required to be published in the Register or have been approved by the Codifier of Rules for publication.

U.S. Department of Justice

Civil Rights Division

JDR:TCH:TGL:par DJ 166-012-3 2003-2633 Voting Section – NWB. 950 Pennsylvania Ave., NW Washington, D.C. 20530

July 15, 2004

Susan K. Nichols, Esq. Special Deputy Attorney General North Carolina Department of Justice 9001 Mail Service Center Raleigh, North Carolina 27699-9001

Dear Ms. Nichols:

This refers to the procedures for conducting the July 20, 2004, special vacancy election, including the absentee voting schedule, for the First Congressional District in the State of North Carolina, submitted to the Attorney General pursuant to Section 5 of the Voting Rights Act, 42 U.S.C. 1973c. We received your submission on June 11, 2004.

The Attorney General does not interpose any objection to the specified changes. However, we note that Section 5 expressly provides that the failure of the Attorney General to object does not bar subsequent litigation to enjoin the enforcement of the changes. In addition, as authorized by Section 5, we reserve the right to reexamine this submission if additional information that would otherwise require an objection comes to our attention during the reminder of the sixty-day review period. See the Procedures for the Administration of Section 5 (28 C.F.R. 51.41 and 51.43).

Sincerely,

Joseph D. Rich Chief, Voting Section

Notice of Application for Innovative Approval of a Wastewater System for On-site Subsurface Use

Pursuant to NCGS 130A-343(g), the North Carolina Department of Environment and Natural Resources (DENR) shall publish a Notice in the NC Register that a manufacturer has submitted a request for approval of a wastewater system, component, or device for on-site subsurface use. The following application has been submitted to DENR:

Application by: William Chandler, President

Chandler Systems, Inc. 220 Ohio Street Ashland, OH 44805 1-800-363-5842 Fax 419-281-2525

For: Pressure Activated Control Liquid Level Controller (PAC)

DENR Contact: Dr. Robert Uebler

1-252-946-6481 FAX 252-975-3716 bob.uebler@ncmail.net

The application may be reviewed by contacting the applicant or at 2728 Capital Blvd., Raleigh, NC, On-Site Wastewater Section, Division of Environmental Health. Draft proposed innovative approvals and proposed final action on the application by DENR can be viewed on the On-Site Wastewater Section web site: www.deh.enr.state.nc/oww/.

Written public comments may be submitted to DENR within 30 days of the date of the Notice publication in the North Carolina Register. All written comments should be submitted to Mr. Bill Jeter, Chief, On-site Wastewater Section, 1642 Mail Service Center, Raleigh, NC 27699-1642, or bill.jeter@ncmail.net, or Fax 919.715.3227. Written comments received by DENR in accordance with this Notice will be taken into consideration before a final agency decision is made on the innovative subsurface wastewater system application.

Note from the Codifier: The notices published in this Section of the NC Register include the text of proposed rules. The agency must accept comments on the proposed rule(s) for at least 60 days from the publication date, or until the public hearing, or a later date if specified in the notice by the agency. If the agency adopts a rule that differs substantially from a prior published notice, the agency must publish the text of the proposed different rule and accept comment on the proposed different rule for 60 days.

Statutory reference: G.S. 150B-21.2.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice is hereby given in accordance with G.S. 150B-21.2 that the Commission for Health Services intends to amend the rule cited as 10A NCAC 41A .0101.

Proposed Effective Date: December 1, 2004

Public Hearing:

Date: September 7, 2004

Time: 2:00 p.m.

Location: Room GIA, 1330 St. Mary's Street, Raleigh, NC

Reason for Proposed Action: It is necessary to amend this rule in order to update those reportable disease and conditions that currently are considered to have the potential to constitute serious public health risks. Prompt reporting of these diseases and conditions is imperative if the Division of Public Health is to take prompt action to prevent or effectively control epidemics in the state.

Procedure by which a person can object to the agency on a proposed rule: Objections may be submitted in writing to Chris G. Hoke, JD, the Rule-Making Coordinator, during the public comment period. Additionally, objections may be made verbally and in writing at the public hearing for this rule.

Written comments may be submitted to: Chris G. Hoke, JD, 1915 MSC, Raleigh, NC 27699-1915, Phone (919)715-4168, email chris.hoke@ncmail.net.

Comment period ends: October 15, 2004

Procedure for Subjecting a Proposed Rule to Legislative Review: Any person who objects to the adoption of a permanent rule may submit written comments to the agency. A person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the 6th business day preceding the end of the month in which a rule is approved. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

Fiscal Impact

| State | Local | Substantive (>\$3,000,000) | None

CHAPTER 41 – HEALTH: EPIDEMIOLOGY

SUBCHAPTER 41A – COMMUNICABLE DISEASE CONTROL

SECTION .0100 – REPORTING OF COMMUNICABLE DISEASES

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

- (a) The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:
 - (1) acquired immune deficiency syndrome (AIDS) 7 days;
 - (2) anthrax 24 hours;
 - (3) botulism 24 hours;
 - (4) brucellosis 7 days;
 - (5) campylobacter infection 24 hours;
 - (6) chancroid 24 hours;
 - (7) chlamydial infection (laboratory confirmed)
 7 days; cholera 24 hours;
 - (9) Creutzfeldt-Jakob disease 7 days;
 - (10) cryptosporidiosis 24 hours;
 - (11) cyclosporiasis 24 hours;
 - (12) dengue 7 days;
 - (13) diphtheria 24 hours;
 - (14) Escherichia coli, shiga toxin-producing 24 hours;
 - (15) ehrlichiosis 7 days;
 - (16) encephalitis, arboviral 7 days;
 - (17) enterococci, vancomycin resistant, from normally sterile site 7 days;
 - (18)(17) foodborne disease, including but not limited to Clostridium perfringens, staphylococcal, and Bacillus cereus 24 hours;
 - (19)(18) gonorrhea 24 hours;
 - (20)(19) granuloma inguinale 24 hours;
 - (21)(20) Haemophilus influenzae, invasive disease 24 hours;
 - (22)(21) Hantavirus infection 7 days;
 - (23)(22) Hemolytic-uremic syndrome/thrombotic thrombocytopenic purpura 24 hours;
 - (24)(23) Hemorrhagic fever virus infection 24 hours;
 - (25)(24) hepatitis A 24 hours;
 - (26)(25) hepatitis B 24 hours;
 - (27)(26) hepatitis B carriage 7 days;

- (28)(27) hepatitis C, acute 7 days;
- (29)(28) human immunodeficiency virus

(HIV) infection confirmed - 7 days;

- (29) influenza virus infection causing death, if < 18 years of age 24 hours;
- (30) legionellosis 7 days;
- (31) leprosy 7 days;
- (31)(32) leptospirosis 7 days;
- (32)(33) listeriosis 24 hours;
- (33)(34) Lyme disease 7 days;
- (34)(35) lymphogranuloma venereum 7 days;
- (35)(36) malaria 7 days;
- (36)(37) measles (rubeola) 24 hours;
- (37)(38) meningitis, pneumococcal 7 days;
- (38)(39) meningococcal disease 24 hours;
- (39)(40) monkeypox 24 hours;
- (40)(41) mumps 7 days;
- (41)(42) nongonococcal urethritis 7 days;
- (42)(43) plague 24 hours;
- (43)(44) paralytic poliomyelitis 24 hours;
- (44)(45) psittacosis 7 days;
- (45)(46) Q fever 7 days;
- (46)(47) rabies, human 24 hours;
- (47)(48) Rocky Mountain spotted fever 7 days;
- (48)(49) rubella 24 hours;
- (49)(50) rubella congenital syndrome 7 days;
- (50)(51) salmonellosis 24 hours;
- (51)(52) severe acute respiratory syndrome (SARS) 24 hours;
- (52)(53) shigellosis 24 hours;
- (53)(54) smallpox 24 hours;
- (55) Staphylococcus aureus with reduced susceptibility to vancomycin 24 hours:
- (54)(56) streptococcal infection, Group A, invasive disease 7 days;
- (55)(57) syphilis 24 hours;
- (56)(58) tetanus 7 days;
- (57)(59) toxic shock syndrome 7 days;
- (58)(60) toxoplasmosis, congenital 7 days;
- (59)(61) trichinosis 7 days;
- (60)(62) tuberculosis 24 hours;
- (61)(63) tularemia 24 hours;
- (62)(64) typhoid 24 hours;
- (63)(65) typhoid carriage (Salmonella typhi) 7 days;
- (64)(66) typhus, epidemic (louse-borne) 7 days;
- (65)(67) vaccinia 24 hours;
- (68) varicella, primary (chicken pox) 24 hours;
- (66)(69) vibrio infection (other than cholera) 24 hours;
- (67)(70) whooping cough 24 hours;
- (68)(71) yellow fever 7 days.
- (b) For purposes of reporting; reporting confirmed human immunodeficiency virus (HIV) infection is defined as as: a positive virus culture; repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test; positive polymerase chain reaction (PCR) nucleic acid detection (NAT) test; or other confirmed testing method approved by the Director of the State Public Health Laboratory conducted on or after February 1, 1990. In selecting additional

- tests for approval, the Director of the State Public Health Laboratory shall consider whether such tests have been approved by the federal Food and Drug Administration, recommended by the federal Centers for Disease Control and Prevention, and endorsed by the Association of Public Health Laboratories.
- (c) In addition to the laboratory reports for Mycobacterium tuberculosis, Neisseria gonorrhoeae, and syphilis specified in G.S. 130A-139, laboratories shall report:
 - (1) Isolation or other specific identification of the following organisms or their products from human clinical specimens:
 - (A) Any hantavirus or hemorrhagic fever virus.
 - (B) Arthropod-borne virus (any type).
 - (C) Bacillus anthracis, the cause of anthrax.
 - (D) Bordetella pertussis, the cause of whooping cough (pertussis).
 - (E) Borrelia burgdorferi, the cause of Lyme disease (confirmed tests).
 - (F) Brucella spp., the causes of brucellosis.
 - (G) Campylobacter spp., the causes of campylobacteriosis.
 - (H) Chlamydia trachomatis, the cause of genital chlamydial infection, conjunctivitis (adult and newborn) and pneumonia of newborns.
 - (I) Clostridium botulinum, a cause of botulism.
 - (J) Clostridium tetani, the cause of tetanus.
 - (K) Corynebacterium diphtheriae, the cause of diphtheria.
 - (L) Coxiella burnetii, the cause of Q fever.
 - (M) Cryptosporidium parvum, the cause of human cryptosporidiosis.
 - (N) Cyclospora cayetanesis, the cause of cyclosporiasis.
 - (O) Ehrlichia spp., the causes of ehrlichiosis.
 - (P) Shiga toxin-producing Escherichia coli, a cause of hemorrhagic colitis, hemolytic uremic syndrome, and thrombotic thrombocytopenic purpura.
 - (Q) Francisella tularensis, the cause of tularemia.
 - (R) Hepatitis B virus or any component thereof, such as hepatitis B surface antigen.
 - (S) Human Immunodeficiency Virus, the cause of AIDS.
 - (T) Legionella spp., the causes of legionellosis.
 - (U) Leptospira spp., the causes of leptospirosis.

- (V) Listeria monocytogenes, the cause of listeriosis.
- (W) Monkeypox.
- (X) Mycobacterium leprae, the cause of leprosy.
- (X)(Y) Plasmodium falciparum, P. malariae, P. ovale, and P. vivax, the causes of malaria in humans.
- (Y)(Z) Poliovirus (any), the cause of poliomyelitis.
- (Z)(AA) Rabies virus.
- (AA)(BB) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
- (BB)(CC) Rubella virus.
- (CC)(DD) Salmonella spp., the causes of salmonellosis.
- (DD)(EE) Shigella spp., the causes of shigellosis.
- (EE)(FF) Smallpox virus, the cause of smallpox.
- (GG) Staphylococcus aureus with reduced susceptibility to vanomycin.
- (FF)(HH) Trichinella spiralis, the cause of trichinosis.
- (GG)(II) Vaccinia virus.
- (HH)(JJ) Vibrio spp., the causes of cholera and other vibrioses.
- (II)(KK) Yellow fever virus.
- (JJ)(LL) Yersinia pestis, the cause of plague. Isolation or other specific identification of the
- (2) Isolation or other specific identification of the following organisms from normally sterile human body sites:
 - (A) Group A Streptococcus pyogenes (group A streptococci).
 - (B) Haemophilus influenzae, serotype b.
 - (C) Neisseria meningitidis, the cause of meningococcal disease.
 - (D) Vancomycin-resistant Enterococcus spp.
- (3) Positive serologic test results, as specified, for the following infections:
 - (A) Fourfold or greater changes or equivalent changes in serum antibody titers to:
 - (i) Any arthropod-borne viruses associated with meningitis or encephalitis in a human.
 - (ii) Any hantavirus or hemorrhagic fever virus.
 - (iii) Chlamydia psittaci, the cause of psittacosis.
 - (iv) Coxiella burnetii, the cause of Q fever.
 - (v) Dengue virus.
 - (vi) Ehrlichia spp., the causes of ehrlichiosis.
 - (vii) Measles (rubeola) virus.
 - (viii) Mumps virus.

- (ix) Rickettsia rickettsii, the cause of Rocky Mountain spotted fever.
- (x) Rubella virus.
- (xi) Yellow fever virus.
- (B) The presence of IgM serum antibodies to:
 - (i) Chlamydia psittaci
 - (ii) Hepatitis A virus.
 - (iii) Hepatitis B virus core antigen.
 - (iv) Rubella virus.
 - (v) Rubeola (measles) virus.
 - (vi) Yellow fever virus.
- (4) Laboratory results from tests to determine the absolute and relative counts for the T-helper (CD4) subset of lymphocytes that have a level below that specified by the Centers for Disease Control and Prevention as the criteria used to define an AIDS diagnosis.

Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141.

TITLE 21 – OCCUPATIONAL LICENSING BOARDS

CHAPTER 14 – BOARD OF COSMETIC ART EXAMINERS

Notice is hereby given in accordance with G.S. 150B-21.2 that the North Carolina State Board of Cosmetic Art Examiners intends to amend the rules cited as 21 NCAC 14A .0101; 14G .0102; 14H .0108, .0121; 14I .0105; 14J .0102, .0502; 14K .0101; 14L .0210; 14R .0101, .0104.

Proposed Effective Date: December 1, 2004

Public Hearing:

Date: September 2, 2004

Time: 10:00 a.m.

Location: State Board of Cosmetic Art, 1201-110 Front St.,

Raleigh, NC

Reason for Proposed Action: Rule updates for Departmental Rules, School Req., Sanitation, School Operations, Cosmetology Curriculum, Manicurist Curriculum, and Continue Education.

Procedure by which a person can object to the agency on a proposed rule: If you have any objection(s) to the proposed rules, please forward a typed or handwritten letter indicating your specific reason(s) for your objections(s) to the following addressing: Souk Rios, NC Board of Cosmetic Art Examiners, 1201 Front St., Suite 110, Raleigh, NC 27609.

Written comments may be submitted to: *Souk Rios, 1201-110 Front St., Raleigh, NC 27609, phone (919) 733-4117, ext. 222, fax (919) 733-4127, and email srios@intrex.net.*

Comment period ends: October 15, 2004

Procedure for Subjecting a Proposed Rule to Legislative Review: Any person who objects to the adoption of a permanent rule may submit written comments to the agency. A person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the 6th business day preceding the end of the month in which a rule is approved. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

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	State
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	Substantive (>\$3,000,000)
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SUBCHAPTER 14A - DEPARTMENTAL RULES

SECTION .0100 - ORGANIZATION RULES

21 NCAC 14A .0101 DEFINITIONS

The following definitions apply in this Chapter:

- (1) "Beauty Establishment" refers to both cosmetic art schools and cosmetic art shops.
- (2) "Cosmetology School" is any cosmetic art school that teaches cosmetic art as defined by, G.S. 88B-2(5), but is not a manicurist or an esthetics school.
- (3) "Cosmetology Student" is a student in any cosmetic art school whose study is the full curriculum.
- (4) "Manicurist School" is a cosmetic art school that teaches only the cosmetic arts of manicuring.
- (5) "Manicurist Student" is a student in any cosmetic art school whose study is limited to the manicurist curriculum set forth in 21 NCAC 14K .0102.
- (6) "Successful Completion" is the completion of an approved cosmetic art curriculum with a minimum grade of "C" or 70%, whichever is deemed as passing by the cosmetic art school.
- (7) "Esthetician School" is any cosmetic art school that teaches only the cosmetic arts of skin care.
- (8) "Esthetician Student" is a student in any cosmetic art school whose study is limited to the esthetician curriculum set forth in 21 NCAC 14O, 0102.
- (9) "Esthetics" refers to any of the following practices: giving facials, applying makeup, performing skin care, removing superfluous

hair from the body of any person by the use of depilatories, tweezers or waxing, or applying eyelashes to any person (this is to include brow and lash color), beautifying the face, neck, arms or upper part of the human body, by use of cosmetic preparations, antiseptics, tonic, lotions or creams, massaging, cleaning, or stimulating the face, neck, ears, arms, hands, bust, torso, legs or feet, by means of the hands, devices, apparatus, or appliances, with the use of cosmetic preparations, antiseptics, tonics, lotions or creams.

- (10) "Natural hair braiding" is a service that results intension on hair strands or roots by twisting, wrapping, weaving, extending, locking, or braiding by hand or mechanical device, provided that the service does not include hair cutting or the application of dyes, reactive chemicals, or other preparations to alter the color of the hair or to straighten, curl, or alter the structure of the hair.
- (11) "Natural hair styling" is the provision of natural hair braiding services together with any of the services or procedures defined within the regulated practice of cosmetic art, and is subject to regulation pursuant to G.S. 88B, and those persons practicing natural hair styling shall obtain and maintain a cosmetologist license as applicable to the services offered or performed. Establishments offering natural hair styling services shall be licensed as cosmetic art shops.
- (12) "Licensing cycle" for cosmetologists, is the three-year period beginning on the first day of October 2004 and ending on the 30th day of September 2007, and continuing thereafter in three year intervals. For estheticians and manicurists the licensing cycle is one year in length beginning on the first day of October and ending on the 30th day of September. For teachers, the licensing cycle is the two-year period beginning on the first day of October of an even-numbered year and ending on the 30th day of September of an even-numbered year.
- (13) "Provider" is a nonprofit professional cosmetic art association, community college, high school, vocational school, postsecondary proprietary school of cosmetic art licensed by the Board, manufacturer of supplies or equipment used in the practice of cosmetic art, the State Board or an agent of the State Board, or any individual or entity that owns and operates five or more licensed salons or that employs at least 50 licensees.

Authority G.S. 88B-2; 88B-4.

SUBCHAPTER 14G - REQUIREMENTS FOR THE ESTABLISHMENT OF COSMETIC ART SCHOOLS

SECTION .0100 - PERMANENT FILES

21 NCAC 14G .0102 FORMS

Application forms may be obtained by writing the North Carolina State Board of Cosmetic Art Examiners, 1201 Front Street, Suite 110, Raleigh, North Carolina 27609.

Authority G.S. 88-23.

SUBCHAPTER 14H - SANITATION

SECTION .0100 - SANITATION

21 NCAC 14H .0108 FLOOR COVERINGS

All floor coverings shall be nonabsorbent and kept clean and in good repair.

Authority G.S. 88-23.

21 NCAC 14H .0121 PROHIBITED PRACTICES

Licensed cosmetologists, estheticians, and manicurists shall not use or possess in a shop any of the following products:

- (1) Methyl Methacrylate Liquid Mononer a.k.a. MMA; and
- (2) Razor-type callus shavers designed and intended to cut growths of skin such as corns and calluses.

Authority G.S. 88B-4.

SUBCHAPTER 14I - OPERATIONS OF SCHOOLS OF COSMETIC ART

SECTION .0100 - RECORD KEEPING

21 NCAC 14I .0105 TRANSFER OF CREDIT

- (a) In order that hours may be transferred from one cosmetic art school to another, a student must pass an entrance examination given by the school to which the student is transferring.
- (b) A cosmetology student must complete at least 500 hours in the cosmetic art school certifying his or her application for the state board examination.
- (c) Upon written petition by the student, the Board shall make an exception to the requirements set forth in Paragraph (b) of this Rule if the student shows that circumstances beyond the student's control prohibited him or her from completing 500 hours at the school that certifies his or her application.
- (d) A student who transfers from a cosmetology curriculum to a manicuring or an esthetics curriculum shall not receive credit for hours received in the cosmetology curriculum.
- (e) A student who transfers from a manicurist or an esthetic curriculum to a cosmetology curriculum shall not receive credit for hours received in the manicurist or an esthetic curriculum.
- (f) If a student is transferring from another state, the student shall submit certification of hours and performances to the cosmetic art school in which they are enrolled.

Authority G.S. 88B-4.

SUBCHAPTER 14J - COSMETOLOGY CURRICULUM

SECTION .0100 - BEGINNERS' DEPARTMENT

21 NCAC 14J .0102 UNIFORM

All students must wear a clean washable uniform or white professional attire and clean, solid shoes while in a cosmetology school.

Authority G.S. 88-23; 88-26(1).

SECTION .0500 – CREDIT FOR COSMETOLOGY STUDY OUTSIDE OF NORTH CAROLINA

21 NCAC 14J .0502 APPROVAL OF CREDIT FOR COSMETOLOGY INSTRUCTION/ANOTHER COUNTRY

Any person who has been trained in the field of cosmetology in a foreign country and desires to be licensed must first demonstrate satisfactory proof of proficiency in the cosmetology skills meeting all the North Carolina requirements. Each applicant must take the State Board examination in the English, Spanish, or Vietnamese language.

Authority G.S. 88-10; 88-12; 88-13; 145-12.

SUBCHAPTER 14K - MANICURIST CURRICULUM

SECTION .0100 - MANICURIST CURRICULUM

21 NCAC 14K .0101 UNIFORMS

All students in training as manicurists shall wear a clean washable uniform or professional attire, nametag identifying academic status, and clean, solid shoes.

Authority G.S. 88-8; 88-23.

SUBCHAPTER 14L - COSMETIC ART TEACHERS

SECTION .0200 - TEACHER PROGRAM AND CURRICULUM

21 NCAC 14L .0210 EFFECT ON STUDENT-TEACHER RATIO

- (a) A student who is either a cosmetology or manicurist teacher trainee need not be counted as a student in computing the allowable student-teacher ratio set by 21 NCAC 14G .0113. However, a cosmetic art school must have at least:
 - (1) One cosmetology teacher for every five cosmetology teacher trainees, or cosmetologist, manicurist, and esthetician trainees combined; or
 - (2) For manicurist teacher trainees only, one cosmetology or manicurist teacher for every five manicurist teacher trainees.
- (b) A cosmetic art school may not count a teacher trainee as a cosmetic art teacher in computing the allowable student-teacher ratio set by 21 NCAC 14G .0113. Teachers included in the ratio

determined under 21 NCAC 14G .0113 may be included in computing the ratio required by this Rule.

Authority G.S. 88B-4.

SUBCHAPTER 14R - CONTINUING EDUCATION

21 NCAC 14R .0101 CONTINUING EDUCATION REQUIREMENTS

- (a) The continuing education requirement for all licensees is eight hours per year. Cosmetologists may complete up to 24 hours of continuing education for each year of the licensing cycle. No licensee shall receive credit for course duplication completed during the licensing cycle. Course instructors shall not receive credit for any course taught by them.
- (b) Courses completed prior to an individual being licensed by the Board shall not qualify for continuing education credit. A licensee shall not receive continuing education credit for any course given in North Carolina that does not have the prior approval of the Board.
- (c) Estheticians and manicurists must complete courses in their subject area. Only licensed teachers may complete courses in teacher training techniques.
- (d) All providers shall allow any official representative or employee of the Board entrance into any Board approved continuing education requirement course at no cost to the Board.
- (e) The Board shall keep a current roster of approved continuing education courses. Copies of the roster shall be posted to the Board's website and updated monthly. Additional copies of the roster shall be available to licensees and the public upon request to the Board. Requesting individuals shall provide stamped, self-addressed envelopes.
- (f) Out-of-state continuing education hours shall be submitted for approval to the Board within 30 days of completing the course in order to be acceptable in meeting the annual requirements.

Authority G. S. 88B-4; 88B-21(e).

21 NCAC 14R .0104 LICENSE RENEWAL PROCEDURES

After completion of the continuing education requirements for any licensing cycle the licensee shall forward only the license renewal application and the license renewal fee. The Board will maintain all continuing education attendance information.

Authority G.S. 88B-4; 88B-21(e).

CHAPTER 46 – BOARD OF PHARMACY

Notice is hereby given in accordance with G.S. 150B-21.2 that the North Carolina Board of Pharmacy intends to adopt the rules citied as 21 NCAC 46 .2705-.2706, and amend the rules cited as 21 NCAC 46 .1414, .1501, .1508, .1602, .1612, .1814, .2502, .2702-.2704, .3301.

Proposed Effective Date: December 1, 2004

Public Hearing

Date: September 11, 2004

Time: 2:15 p.m.

Location: General Ballroom, 1st floor of the Wilmington Hilton

Riverside, 301 North Water Street, Wilmington, NC

Reason for Proposed Action:

To require that health care facility pharmacies comply with the same requirements for automated dispensing or drug supply devices as other pharmacies in order to protect the public.

To allow the Board to run a criminal background check on applicants for licensure, reciprocity, and reinstatement, to protect the public from those who might present a danger to the public health, safety, and welfare.

To amend 21 NCAC 46 .1508 so that it reflects the current practice of administration of the disease state management examination by the National Association of Boards of Pharmacy. To allow the Board to place requirements upon applicants for license by reciprocity who have not practiced pharmacy within the previous five years and on applicants for reinstatement to assure that the applicant can safely and properly practice pharmacy.

To revise requirement for automated dispensing or drug supply devices to ensure safety, accuracy, security, and patient confidentiality, and to define access and limits to access to equipment and medications.

To limit starter doses supplied to doctors' offices and to ensure that patents are advised of their right to choose any pharmacy.

To clarify and revise definitions used in rules regulating nuclear pharmacy practice.

To require that only a qualified nuclear pharmacist can obtain a nuclear pharmacy permit to ensure the best interests of patient heal and safety.

To revise requirements for pharmacies providing radiopharmaceutical services to ensure the best interests of patient health and safety.

To set out labeling requirements for radiopharmaceuticals to ensure the best interests of patient health and safety.

To set out prohibitions to avoid contamination to ensure the best interests of patient health and safety.

To set out a data processing fee for renewal of expired pharmacy technician registrations more than 60 days after expiration.

Procedure by which a person can object to the agency on a proposed rule: Persons may submit objections regarding the proposed rule changes to David R. Work, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Written comments may be submitted to: David R. Work, North Carolina Board of Pharmacy, 6015 Farrington Road, Suite 201, Chapel Hill, NC 27517.

Comment period ends: October 15, 2004

Procedure for Subjecting a Proposed Rule to Legislative Review: Any person who objects to the adoption of a permanent

rule may submit written comments to the agency. A person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the 6th business day preceding the end of the month in which a rule is approved. The Commission will receive those objections by mail, delivery service, hand delivery, or facsimile transmission. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 919-733-2721.

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SECTION .1400 - HOSPITALS: OTHER HEALTH FACILITIES

21 NCAC 46 .1414 DRUG DISTRIBUTION AND CONTROL

- (a) MEDICATION ORDERS.
 - (1) Pharmacists shall dispense medications from a health care facility pharmacy only upon receipt of a medication order. A mechanism shall be in place to verify the authenticity of the medication order. Oral orders shall be put in writing immediately and signed within the time frame established by regulatory agencies and health care facility policies and procedures.
 - (2) All medication orders shall be received and reviewed by a pharmacist and, at a minimum, shall contain the:
 - (A) patient's name, location and other necessary identifying information such as history or medical records number;
 - (B) medication name, strength, dosage form, route of and directions for administration. In the absence of a facility policy on interpretation of routes of administration, the route of administration must be specified;
 - (C) date the order was written; and
 - (D) prescriber's signature (may include electronic signature or verification).
 - (3) The health care facility pharmacy and the pharmacist-manager shall ensure that medication orders for patients requiring continuous drug therapy shall be entered into a patient medication profile, either manual or automated. The medication profile shall, at a minimum, contain the:

- (A) patient's name, location and important clinical data such as age, height, weight, sex, and allergies;
- (B) medication name, strength, dosage form, route of and directions for administration;
- (C) medication start date;
- (D) medication discontinuance date; and
- (E) identification of pharmacist responsible for or verifying technician entry of the medication order.
- (4) Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.
- (5) Medication orders shall be reviewed and discontinued or suspended, if appropriate, when the patient is transferred to the delivery room, operating room, or is admitted from another facility. A method to protect the patient from indefinite, open-ended drug orders must be provided. The prescriber shall be notified in a timely manner that the order shall be stopped before such action takes place by one or more of the following:
 - (A) the routine monitoring of patient's drug therapy by a pharmacist;
 - (B) a health care facility-approved, drug class-specific, automatic stop order policy covering those drug orders not specifying a number of doses or duration of therapy; or
 - (C) a health care facility-approved automatic cancellation of all drug orders after a predetermined time interval unless rewritten by the prescriber.
- (6) Health care facilities which credential practitioners for prescribing privileges within the facility shall provide the health care facility pharmacy with credentialing information annually or immediately upon discharge or when privileges are suspended or terminated.
- (b) DEVICES. Devices shall be dispensed in accordance with Section .2600 of this Chapter.
- (c) DISPENSING. In health care facilities with 24 hour pharmacy services, all dispensing shall be done by a pharmacist. In health care facilities without 24 hour pharmacy services, Rule .1413 of this Section shall apply in the absence of a pharmacist. (d) LABELING.
 - (1) The health care facility pharmacy and the pharmacist dispensing the drug shall ensure that all drugs dispensed from within a health care facility pharmacy are labeled and identified up to the point of administration;
 - (2) Whenever a drug is added to a parenteral admixture, it shall be labeled with a distinctive

supplementary label indicating the name and amount of the drug added, expiration date, and expiration time, if applicable. For admixtures prepared outside the pharmacy, the pharmacist-manager shall develop policies and procedures for preparation and labeling.

- (e) PARENTERAL MEDICATIONS. The dispensing of parenteral medications shall be done in accordance with Section .2800 of this Chapter--Sterile Parenteral Pharmaceuticals.
- (f) PATIENT CARE UNIT MEDICATION INVENTORIES. This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.
 - (1) The pharmacist-manager shall develop an approved drug list for each health care facility location. Non-controlled drugs may be stocked in quantities limited to not more than five dosage units per drug on a health care facility patient care unit when immediate availability is deemed essential to the patient's health and well-being. Drugs shall be stored in a manner that prevents unauthorized access and shall only be administered to a patient of the health care facility pursuant to a medication order.
 - (2) All controlled substances stocked within a health care facility that are not located within the facility's pharmacy or automated dispensing device must be accompanied by a disposition form issued from the pharmacy. This document shall at a minimum contain:
 - (A) the product name, strength, dosage form, and quantity supplied;
 - (B) the date transferred to the patient care unit by the pharmacy;
 - (C) the name of the pharmacy representative supplying, and the patient care unit representative receiving the drug;
 - (D) the date, time, and amount of the drug removed from the patient care unit stock for administration; and
 - (E) the patient name and identification of the person acquiring the product.
 - (3) Exceptions to this Paragraph shall be made for use of automated dispensing devices provided that these devices meet all applicable rules for controlled substances contained therein.
 - (4) When a dose of a controlled substance has been prepared for a patient but not used (i.e., refused, order canceled, or contaminated), it may be destroyed at the patient care unit. The destruction must be witnessed by a health care provider, such as a pharmacist, registered nurse, or licensed practical nurse. The pharmacist-manager shall ensure that details of the event, along with the identification of the two who effected the destruction, are documented. If such record is separate from the disposition form, it shall be maintained

uniformly with the corresponding disposition form.

- (g) ANCILLARY DRUG CABINET INVENTORIES. (This Paragraph does not apply to nursing facilities, assisted living facilities, and adult care homes.) Drugs that are routinely prescribed by the medical staff in a health care facility shall be maintained in quantities limited to not more than five dosage units per drug as a supplementary inventory for use only when the pharmacy is closed. The pharmacist-manager shall, in connection with the appropriate committee of the health care facility, develop listings of those drugs to be included in such inventories. The pharmacist-manager shall, at a minimum, assure that:
 - (1) access to such drug inventories is by locked cabinet(s) or other enclosure(s) constructed and secured to deny access to unauthorized persons;
 - only authorized personnel, as indicated by written policies and procedures, shall obtain access to the drug inventories;
 - (3) only pre-packaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements. Drugs shall be properly labeled, with drug name, strength, lot number and expiration date. Whenever access to such inventory is gained, a copy of the record of withdrawal and a copy of the written order for new drug orders shall be provided to the pharmacy. The record of withdrawal shall contain the following:
 - (A) the date of removal of the drug;
 - (B) the name, strength, dosage form, and quantity of drug removed;
 - (C) the name of the patient for whom the drug was ordered;
 - (D) the name or identification code of the authorized personnel removing the drug from inventory;
 - (4) all drugs are reviewed no less often than quarterly to ensure their purity, potency, and integrity; and
 - (5) written policies and procedures are established to implement the requirements of this Rule.
- (h) AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES. Automated Dispensing or Drug Supply Devices such as but not limited to Pyxis machines may be utilized in health care facility pharmacies and where a pharmacy permit exists provided that the pharmacist manager has developed procedures to assure safe and effective use of medications in accordance with 21 NCAC 46 .1814.
- (i) EMERGENCY KITS. (This Paragraph does not apply to adult care homes or assisted living facilities) Drugs and devices may be provided in emergency kits for use by authorized personnel provided the pharmacist-manager, in conjunction with the medical staff of the health care facility, develop and implement written policies and procedures to ensure compliance with the following provisions:
 - (1) the pharmacist-manager, or designee, and the medical staff of the health care facility jointly

- determine the drugs and devices, by identity and quantity, to be included in the kit. Drugs and devices included in the kit shall be limited to those for emergency use only and are not to be used for any other purpose.
- (2) the emergency kit contains those drugs and devices which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent prolonged discomfort or risk of harm to patients;
- (3) the emergency kit shall be stored in a secure, readily available location under the supervision of the nursing staff and sealed with a non-reusable, removable seal to prevent unauthorized access, and to ensure a proper environment for preservation of the drugs and devices within them. Policies and procedures shall be established to ensure the integrity of the kit at all times;
- (4) the exterior of the emergency kit shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only. In addition, a listing of the drugs and devices contained therein, including name, strength, and quantity of each drug or device shall be attached. Each emergency kit shall be inspected by a pharmacist or his designee every 30 days (90 days for long-term care facilities) to check for expiration dates and the integrity of the seal;
- (5) all drugs and devices contained within the emergency kit shall be labeled, if applicable, with, at a minimum, the name, strength, lot number, manufacturer, and expiration date;
- (6) drugs and devices shall be removed from the emergency kit for administration to a patient only pursuant to a valid physician's order, by personnel authorized by the facility;
- (7) whenever an emergency kit is opened, the pharmacy shall be notified. The pharmacist-manager or designee shall re-stock, re-seal, and return the kit to the unit within a reasonable length of time in order to prevent risk of harm to patients. The emergency drug kits shall be checked by an authorized person in accordance with written policies and procedures of the health care facility. In the event the kit is opened in an unauthorized manner, the pharmacy and other personnel designated by the pharmacist-manager of the facility shall be notified; and
- (8) Emergency drugs that are controlled substances must be stored in compliance with 10 NCAC 45G .0410.

(j) RECORDS.

(1) The pharmacist-manager shall, in addition to the requirements for preserving prescription

- orders as set forth in G.S. 90-85.26, develop a system of daily accountability for medication compounding and dispensing that shall permit identification of the responsible pharmacists and pharmacy technicians. Readily retrievable records of accountability shall be maintained for at least 30 days. At a minimum, this system shall identify all personnel who perform these activities and the pharmacist responsible for:
- (A) interpretation and appropriateness of new medication orders;
- (B) profile entry of new medication orders;
- (C) dispensing of new medication orders including stat doses;
- (D) daily cart fills;
- (E) intravenous admixtures;
- (F) compounded medications; and
- (G) periodically assessing the quality of pharmacy procedures for preparation and release of drugs and devices for replenishment of floor stock, ancillary drug supplies, and automated dispensing devices in locations outside the pharmacy.
- (2) Upon notification of medication errors resulting from the administration of an incorrect medication or dose, the pharmacist-manager shall document such medication error. Documentation shall include pertinent chronological information and include documentation on health care facility forms. These documents shall be archived in a readily retrievable manner, open for inspection, for a period of three years.
- (3) Upon notification of information that reasonably suggests that there is a probability a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient (see 21 NCAC 46 .2502(k) RESPONSIBILITY OF PHARMACIST-MANAGER), the pharmacist-manager shall retain all documents, labels, vial, supplies, substances and internal investigative reports relating to the event. All such items shall be maintained by the health care facility, accessible to the pharmacist-manager, and open to the Board of Pharmacy.
- (4) The pharmacist-manager shall maintain records of ordering, receiving, dispensing or transfer of controlled substances. These records shall include, but are not limited to the following:
 - (A) Invoices or other such documents verifying the ordering and receipt of controlled substances;
 - (B) Perpetual inventories of controlled substances transferred to patient care

units and other sites as allowed by this Rule (i.e., automated dispensing devices, emergency kits, etc.). These inventories shall record the transfer date; location transferred to; the identity of the drug; strength, dosage form, and quantity transferred; transferring pharmacist's name;

- (C) Disposition records required by Paragraph (f)(4) of this Rule;
- (D) A record of controlled substances dispensed directly to the patient to include the patient's name; date dispensed; dispensing pharmacist's name; name, strength, dosage form, and quantity of the drug dispensed. The records shall also document drugs returned and credited; and
- (D) A perpetual inventory shall be maintained on all controlled substances awaiting destruction or return to a vendor.
- (5) Automated systems may be used to collect and store information required by Subparagraph (j)(4) of this Rule provided such system allows for the immediate retrieval (via CRT display and hard-copy printout) of original medication order information and dispensing history consistent with criteria cited in 21 CFR .1306 and 10 NCAC 46 .2304.
- (6) With the exception of Subparagraph (j)(l) of this Rule, all records required by this Section shall be maintained for a period of three years. Such records shall be archived in a uniform manner, retrievable to the pharmacy within 48 hours, and open for review, copying, or seizure by a member or designated employee of the Board.

Authority G.S. 90-85.6; 90-85.21; 90-85.32; 90-85.33; 90-85.34.

SECTION .1500 - ADMISSION REQUIREMENTS: EXAMINATIONS

21 NCAC 46 .1501 APPLICATION

(a) All applications for examination shall be made on forms provided by the Board, filed with the Board 45 days prior to the date of the examination, and accompanied by the required fee.
(b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.

Authority G.S. 90-85.6; 90-85.15; 90-85.24.

21 NCAC 46 .1508 PREREQUISITES FOR DISEASE STATE MANAGEMENT EXAMINATION

In order to apply for the disease state management examination administered by the Board, National Association of Boards of

<u>Pharmacy</u>, a pharmacist must be a North Carolina licensed pharmacist.

Authority G.S. 90-85.6; 90-85.34.

SECTION .1600 - LICENSES AND PERMITS

21 NCAC 46,1602 LICENSE BY RECIPROCITY

- (a) An applicant for licensure without examination, must have:
 - (1) Originally been licensed as a pharmacist by an examination equivalent to the North Carolina examination specified in Rule .1505(a)(1) of this Chapter;
 - (2) Achieved scores on an equivalent examination, such as the NABPLEX examination, which would qualify for licensure in this state at the time of examination; and
 - (3) Been licensed by a state which deems licensees from this state to be equivalent to the extent that they are suitable for licensure in that state without further substantial examination.
- (b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.
- (c) The Board may require an applicant for licensure without examination who has not practiced pharmacy within the previous five years to obtain additional practical experience and continuing education. The Board may also restrict licenses granted pursuant to this Paragraph for such period of time as the Board deems necessary to assure that the applicant can safely and properly practice pharmacy.

Authority G.S. 90-85.6; 90-85.20.

21 NCAC 46.1612 REINSTATEMENT OF LICENSES AND PERMITS

- (a) All licenses renewed after March 1 are subject to the maximum original fee set out in G.S. 90-85.24 for applicants for licensure. All permits renewed after March 1 are subject to the original registration fee.
- (b) All applicants shall submit to the Board a signed release form, completed Fingerprint Record Card, and such other form(s) required to perform a criminal history check at the time of application.
- (c) The Board may require applicants for reinstatement pursuant to G.S. 90-85.19 to obtain additional practical experience and continuing education. The Board may also restrict licenses reinstated pursuant to G.S. 90-85.19 for such period of time as the Board deems necessary to assure that the applicant can safely and properly practice pharmacy.

Authority G.S. 90-85.19; 90-85.24.

SECTION .1800 - PRESCRIPTIONS

21 NCAC 46 .1814 AUTOMATED DISPENSING OR DRUG SUPPLY DEVICES

- (a) Automated dispensing or drug supply devices may be used in health care facility pharmacies and where a pharmacy permit exists, for maintaining patient care unit medication inventories or for a patient profile dispensing system, provided the utilization of such devices is under the supervision of a pharmacist. The pharmacist manager shall develop and implement procedures to assure safe and effective use of medications, and, at a minimum, shall assure that:
 - (1) only authorized personnel, as indicated by written policies and procedures, may obtain access to the drug inventories;
 - (2) all drugs therein are reviewed no less than monthly:
 - (3) a system of accountability must exist for all drugs contained therein; the purity, potency, and integrity of the drugs shall be preserved;
 - (4) the device provides records required by this Section and other applicable laws and rules;
 - (5) requirements for controlled substances security are met; and
 - (6) prior to the drug being released for access by the nurse, the pharmacist enters the medication order into a computerized pharmacy profile that is interfaced to the automated dispensing unit, so that drug allergy screening, therapeutic duplication, and appropriate dose verification is done prior to the drug being administered.
- (b) Notwithstanding the provisions of Rule 21 NCAC 46 .2501, a pharmacist is required to supervise only the following activities pursuant to this Rule:
 - (1) The packaging and labeling of drugs to be placed in the dispensing devices. Such packaging and labeling shall conform to all requirements pertaining to containers and label contents:
 - (2) The placing of previously packaged and labeled drug units into the dispensing device; and
 - (3) The restocking of automated dispensing devices.
- (c) Only persons authorized by the pharmacist manager may remove drugs from the dispensing devices and only in the quantity of doses needed to satisfy immediate patient needs. Should a violation of the foregoing occur, the pharmacist manager shall conduct an investigation and report any violations to the entity having jurisdiction over these issues.
- (d) Bar code scanning of drug packaging and storage units may be utilized as a quality control mechanism if this technology is available in the automated dispensing system.
- (a) Definitions.
 - "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
 - (A) Distribute medications in a licensed health care facility; or

- (B) Package medications for final distribution by a pharmacist.
- (2) "Centralized automated medication system"

 means an automated medication system
 located in a pharmacy department from which
 medication is distributed or packaged for final
 distribution by a pharmacist.
- (3) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution and at a single location.
- (4) "Distribution" means the process of providing

 a drug to an individual authorized to
 administer medications and licensed as a
 health care provider in the state of North
 Carolina pursuant to an order issued by an
 authorized prescriber.
- (5) "Medication" means a medicinal drug or proprietary preparation.
- (6) "Override medication" means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because the Medical Staff Committee has determined that the clinical status of the patient would be significantly compromised by delay.
- (7) "Low risk override medication" is a medication determined by the Medical Staff Committee to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
- (8) "Physician controlled medication" is a medication ordered, prepared or administered by a physician.
- (b) General Requirements for the Use of Automated Medication Systems.
 - (1) The consultant pharmacist of record or pharmacist-manager shall be responsible for:
 - (A) Maintaining a record of each transaction or operation;
 - (B) Controlling access to the system;
 - (C) Maintaining policies and procedures for:
 - (i) Operating of the automated medication system;
 - (ii) Training personnel who use the automated medication system;
 - (iii) Maintaining patient services
 whenever the automated
 medication system is not
 operating; and
 - (iv) Defining a procedure for a pharmacist to grant access to

the medication in the system or to deny access to the medication in the system;

- (D) Security of the system;
- (E) Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;
- (F) Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;
- (G) Establishing a comprehensive Quality
 Assurance program;
- (H) Establishing a procedure for stocking or restocking the automated medication system; and
- (I) Insuring compliance with all requirements for packaging and labeling.
- (2) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk medication or a physician controlled medication.
- (3) A pharmacist shall perform retrospective drug use review for an override medication.
- (c) <u>Medical Staff Committee for Decentralized Automated</u> Medication Systems.
 - (1) The consultant pharmacist of record or pharmacist-manager shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.
 - (2) The Medical Staff Committee shall:
 - (A) Include at least one pharmacist;
 - (B) Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system; and
 - (C) Develop policies and procedures regarding the decentralized automated medication system.
- (d) Stocking or Restocking of an Automated Medication System.
 - (1) Medications in an Automated Medication

 Systems shall be stocked or restocked by a pharmacist or by a pharmacy technician supervised by a pharmacist.
 - (2) The stocking or restocking of an automated medication system shall follow one of the following procedures to assure correct medication selection:
 - (A) A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication

- system that includes random sampling.
- (B) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation, followed by a monthly quality assurance review by a pharmacist.
- (3) The pharmacist performing the quality assurance review shall maintain a record of the quality assurance process that occurred and the pharmacist approval of the medication stocking, restocking or verification process.
- (e) Medication Reuse. Medication that has been removed from the automated medication system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.
- (f) Centralized Automated Medication Systems. A pharmacist utilizing a centralized automated medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:
 - (1) The initial medication order has been reviewed and approved by a pharmacist; and
 - (2) The medication is distributed for subsequent administration by a health care professional permitted by North Carolina law to administer medication.
- (g) Quality Assurance Program. The consultant pharmacist of record or pharmacist-manager shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:
 - (1) Review of override and low risk override medication utilization;
 - (2) Investigation of a medication error related to the automated medication system;
 - (3) Review of a discrepancy or transaction reports
 and identify patterns of inappropriate use or
 access:
 - (4) Review of the operation of the system;
 - (5) Integration of the automated medication system quality assurance program with the overall continuous quality improvement program of the pharmacy; and
 - (6) Assurance that individuals working with the automated medication system receive appropriate training on operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(h) Record Keeping.

(1) The consultant pharmacist of record or pharmacist-manager shall maintain records

- <u>related to the automated medication system for</u> the system in a readily retrievable manner.
- (2) The following records shall be maintained for at least 60 days:
 - (A) Daily audits of stocking or restocking, if applicable;
 - (B) Daily audits of the output of a centralized automated medication system, if applicable; and
 - (C) Transaction records for all noncontrolled medications or devices distributed by the automated medication system.
- (3) The following records shall be maintained for at least two years:
 - (A) Any report or analysis generated as part of the quality assurance program;
 - (B) A report or database related to access
 to the system or any change in the
 access to the system or access to
 medication in the system; and
 - (C) Transaction records from the automated medication system for all controlled substances dispensed or distributed.
- (i) Compliance. The consultant pharmacist of record or pharmacist-manager shall assure compliance with all requirements of the Pharmacy Practice Act and Board rules.

Authority G.S. 90-85.6; 90-85.32; 90-85.33.

SECTION .2500 - MISCELLANEOUS PROVISIONS

21 NCAC 46 .2502 RESPONSIBILITIES OF PHARMACIST-MANAGER

- (a) The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.
- (b) The pharmacist-manager employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance but shall be present for at least one-half the hours the pharmacy is open or 32 hours a week, whichever is less.
- (c) Whenever a change of ownership or change of pharmacist-manager occurs, the successor pharmacist-manager shall complete an inventory of all controlled substances in the pharmacy within 10 days. A written record of such inventory, signed and dated by the successor pharmacist-manager, shall be maintained in the pharmacy with other controlled substances records for a period of three years.
- (d) The pharmacist-manager shall develop and implement a system of inventory record-keeping and control which will enable that pharmacist-manager to detect any shortage or discrepancy in the inventories of controlled substances at that pharmacy at the earliest practicable time.
- (e) The pharmacist-manager shall maintain complete authority and control over any and all keys to the pharmacy and shall be responsible for the ultimate security of the pharmacy. A pharmacy shall be secured to prohibit unauthorized entry if no

- pharmacist will be present in the pharmacy for a period of 90 minutes or more.
- (f) These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments as set forth in the Rules in this Chapter.
- (g) A person shall not serve as pharmacist-manager at more than one pharmacy at any one time except for limited service pharmacies.
- When a pharmacy is to be closed permanently, the pharmacist-manager shall inform the Board and the United States Drug Enforcement Administration of the closing, arrange for the proper disposition of the pharmaceuticals and return the pharmacy permit to the Board's offices within 10 days of the closing date. Notice of the closing shall be given to the public by posted notice at the pharmacy at least 30 days prior to the closing date and, if possible, 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacistmanager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request. Absent specific patient or customer, instructions from the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy for maintenance of patient therapy and shall inform the public of such transfer by posted notice at the pharmacy for 15 days after the closing date, if possible. Controlled substance records shall be retained for the period of time required by law.
- (i) The pharmacist-manager shall ensure that notice of the temporary closing of any pharmacy for more than 14 consecutive days is given to the public by posted notice at the pharmacy at least 30 days prior to the closing date, and, if possible, 15 days after the closing date. Such notice shall notify the public that prescription files may be transferred to a pharmacy of the patient's or customer's choice during the 30 day period prior to the closing date. During the 30 day period prior to the closing date, the pharmacist-manager, and the pharmacy's owner (if the owner is other than the pharmacist-manager), shall transfer prescription files to another pharmacy chosen by the patient or customer, upon request.
- (j) The pharmacist-manager shall prepare a plan to safeguard prescription records and pharmaceuticals in the event of a natural disaster such as hurricane or flood.
- (k) The pharmacist-manager shall separate from the dispensing stock all drug products more than six months out of date.
- (l) The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall retain all documents, labels, vials, supplies, substances and internal investigative reports relating to the event. All such items shall be made available to the Board upon request.

- (m) The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this Rule, except as required by law. All reports made under Paragraph (l) of this Rule shall not be released except as required by law.
- (n) Dispensing errors which are not detected and corrected prior to the patient receiving the medication shall be documented and reported to the pharmacist-manager. Documentation shall include pertinent chronological information and appropriate forms including the identity of individual(s) responsible. These documents, including action taken as part of a quality assurance plan, shall be archived in a readily retrievable manner and open for review, copying or seizure by the Board or its designated employees within 48 hours of a request for inspection for a period of three years. These documents shall be released only to the Board or its designated employees pursuant to an investigation and shall not otherwise be released except as required by law. Upon request by the Board or its designated employees, these documents shall be transmitted by the pharmacist-manager to an office of the Board.
- (o) In any Board proceeding, the Board shall consider compliance with Paragraphs (l) and (n) of this Rule as a mitigating factor and noncompliance with Paragraphs (l) and (n) of this Rule as an aggravating factor.
- (p) The pharmacist-manager shall ensure that all starter doses of medication supplied to doctors' offices are accompanied by written materials advising the patient that such doses of medication may be supplied by any pharmacy. Starter doses shall be limited to a twenty-four hour dose supply per patient.

Authority G.S. 90-85.6; 90-85.21; 90-85.25; 90-85.26; 90-85.32.

SECTION .2700 - NUCLEAR PHARMACY

21 NCAC 46 .2702 DEFINITIONS

- (a) Qualified Nuclear Pharmacist. A pharmacist currently licensed by the Board who meets the following standards:
 - (1) Meets minimum standards of training for
 "authorized user status" of radioactive material
 in accordance with the licensure guide of the
 United States Nuclear Regulatory
 Commission:
 - (2) Has received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an approved college of pharmacy, including instruction in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry; and
 - (3) Has a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.
- (b) Qualified Licensed Professional. A non pharmacist, such as a physician, nurse or technologist, who possesses a current state license, if required, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals

- as defined by the respective requirements of the regulations of the NRC.
- (c) Nuclear Pharmacy. A pharmacy providing radiopharmaceutical services, including such areas in a hospital, nursing home, sanitarium or clinic pharmacy.
- (d) Radiopharmaceutical Service. The procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record keeping and disposal of radiopharmaceuticals and other radioactive drugs.
- (e) Radiopharmaceutical Quality Assurance. The performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.
- (f) Internal Test Assessment. Conducting those tests of quality assurance necessary to insure the integrity of the test.
- (g) Authentication of Product History. Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other radioactive drug.
- (h) Radiopharmaceuticals. Radioactive drugs as defined by the United States Food and Drug Administration.
- (i) Nuclear Pharmacy Practice. A patient oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals.
- (a) Authentication of Product History. Identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other radioactive drug.
- (b) Nuclear Pharmacy. A pharmacy holding a permit issued by the North Carolina Board of Pharmacy and licenses issued by the Nuclear Regulatory Commission (NRC) and other state regulatory agencies, where prescriptions for radiopharmaceutical products are filled, compounded, or dispensed.
- (c) Nuclear Pharmacy Practice. A patient-oriented service that embodies the scientific knowledge and professional judgment required to improve and promote health through the assurance of the safe and efficacious use of radiopharmaceuticals.
- (d) Nuclear Pharmacy Technician. Any person involved in the dispensing of a radiopharmaceutical, not satisfying the definition of Qualified Licensed Professional; any such person must be registered as a Pharmacy Technician with the State Board of Pharmacy.
- (e) Qualified Licensed Professional. A non-pharmacist possessing a valid license issued by the North Carolina Medical Board, the North Carolina Board of Nursing, the North Carolina Dental Board or the North Carolina Board of Veterinary Medicine, and who has sufficient training and experience to safely handle and dispense radiopharmaceuticals as defined by the respective requirements of the regulations of the NRC or the state nuclear regulatory agencies.
- (f) Qualified Nuclear Pharmacist. A pharmacist currently licensed by the Board who meets the following standards:
 - (1) Certification as a nuclear pharmacist by the "Board of Pharmaceutical Specialties"; or
 - (2) Meets minimum standards of training for "authorized user status" of radioactive material

in accordance with the licensure guide of the United States Nuclear Regulatory Commission or the appropriate state nuclear regulatory agencies as follows:

- (A) Has received a minimum of 200 contact hours of instruction in nuclear pharmacy and the safe handling and use of radioactive materials from an approved college of pharmacy, including instruction in the following areas: radiation physics and instrumentation; radiation protection; mathematics of radioactivity; radiation biology; and radiopharmaceutical chemistry; and
- (B) Has a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a qualified nuclear pharmacist.
- (g) Radiopharmaceutical Quality Assurance. The performance of appropriate chemical, biological and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.
- (h) Radiopharmaceuticals. Radioactive drugs shall include any article that exhibits spontaneous decay or disintegration of an unstable atomic nucleus, usually accompanied by the emission of ionizing radiation and any nonradioactive reagent kit or nuclide generator that is intended for use in the preparation of any such article.
- (i) Radiopharmaceutical Service. The procurement, storage, handling, preparation, labeling, quality assurance testing, dispensing, delivery, record-keeping and disposal of radiopharmaceuticals and other radioactive materials.
- (j) Test Assessment. Conducting quality assurance evaluation necessary to ensure the integrity of the test.

Authority G.S. 90-85.6; 90-85.34.

21 NCAC 46 .2703 OBTAINING A NUCLEAR PHARMACY PERMIT

In order to obtain a nuclear pharmacy permit, the person seeking such a permit should submit an application to the Board certifying that he or she is a pharmacist currently licensed by the Board and that he or she meets the requirements of is a qualified nuclear pharmacist as specified in Rule .2702 of this Section. The application shall describe in detail the location, time and manner by which the contact hours required by Rule .2702(f)(2)(A)and(B) of this Section were obtained by the applicant and shall be submitted under oath.

Authority G.S. 90-85.6; 90-85.34.

21 NCAC 46 .2704 REQ FOR PHARMACIES PROVIDING RADIOPHARMACEUTICAL SERVICES

(a) The permit to operate a pharmacy providing radiopharmaceutical services shall be issued by the Board only to a qualified nuclear pharmacist. All personnel performing

- tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a qualified nuclear pharmacist. A qualified nuclear pharmacist shall be responsible for all operations of the pharmacy related to radiopharmaceutical services and shall be in personal attendance at all times that the pharmacy renders radiopharmaceutical services.
- (b) In emergency situations, and in the absence of a qualified nuclear pharmacist, designated qualified licensed professionals as identified by the pharmacist-manager in established written policies and procedures may have access to the area designated as the nuclear pharmacy area, and these individuals may prepare single doses of radiopharmaceuticals for the immediate emergency only and must document such activities.
- (c) The nuclear pharmacy area shall be secured from entry by unauthorized personnel personnel as identified by the pharmacist-manager in established written policies and procedures.
- (d) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radiopharmaceuticals in accordance with Section .2300 of this Chapter and the applicable regulations of the North Carolina Division of Radiation Protection.
- (e) All pharmacies handling radiopharmaceuticals shall provide a radioactive storage and product decay area which that provides sufficient protection from radioactivity of all areas surrounding the nuclear pharmacy area. Detailed floor plans shall be submitted to and approved by the Board staff before approval of the a nuclear pharmacy permit. permit is issued.
- (f) Radiopharmaceuticals are to be dispensed only upon a prescription or medication order from a licensed medical practitioner authorized to possess, use and administer radiopharmaceuticals.
- (g) The library of a nuclear pharmacy shall contain, In in addition to other labeling requirements of the Board for non radioactive drugs described in this Chapter, the container of a radiopharmaceutical shall also be labeled with:
 - (1) The standard radiation symbol;
 - (2) The words "CAUTION RADIOACTIVE MATERIALS":
 - (3) The radionuclide of the radiopharmaceutical contained therein;
 - (4) The chemical form of the radiopharmaceutical contained therein;
 - (5) The amount of radioactivity of the radiopharmaceutical contained therein and the date and time of the calibration of that radioactivity:
 - (6) The date and time of the expiration of the radiopharmaceutical contained therein;
 - (7) If the radiopharmaceutical is a liquid, the
 - (8) If the radiopharmaceutical is a solid, the number of capsules or weight contained therein:
 - (9) If the radiopharmaceutical is a gas, the number of ampules, vials, or syringes contained therein:

- (10) The name, address and telephone number of the nuclear pharmacy dispensing the radiopharmaceutical;
- (11) The prescription or lot number; and
- (12) The name of the pharmaceutical.

the volumes required by Rule .1601(a)(3) of this Chapter, copies of current state and federal regulations governing the safe storage, handling, use, dispensing, transport, and disposal of radiopharmaceuticals.

- (h) All pharmacies performing Radiopharmaceutical Services shall have in effect a procedures manual setting forth the procedures and policies of the pharmacy regarding Radiopharmaceutical Quality Assurance. This manual shall at all times be readily available for review by Board personnel.
- (i) The application for a permit to operate a nuclear pharmacy must be accompanied by certification that the applicant is the holder of a current approved license Permit holders must obtain licensure from the North Carolina Division of Radiation Protection and the number of that license. Copies of the Division's inspection report shall be made available upon request for inspection by Board personnel.
- (j) The library of a nuclear pharmacy shall contain, in addition to the volumes required by Rule .1601(a)(4)(K) of this Chapter, copies of current state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.
- (k) All pharmacies performing Radiopharmaceutical Services shall have in effect a procedures manual setting forth the procedures and policies of the pharmacy regarding Radiopharmaceutical Quality Assurance. This manual shall at all times be readily available for review by Board personnel.

Authority G.S. 90-85.6; 90-85.34.

21 NCAC 46 .2705 LABELING REQUIREMENTS OF RADIOPHARMACEUTICALS

- (a) In addition to other labeling requirements of the Board for non-radioactive drugs described in this Chapter, the container of a radiopharmaceutical shall also be labeled with:
 - (1) The standard radiation symbol;
 - (2) The words "CAUTION RADIOACTIVE MATERIALS";
 - (3) The radionuclide of the radiopharmaceutical contained therein;
 - (4) The chemical form of the radiopharmaceutical contained therein;
 - (5) The amount of radioactivity of the radiopharmaceutical contained therein and the date and time of the calibration of that radioactivity;
 - (6) The date and time of the expiration of the radiopharmaceutical contained therein;
 - (7) If the radiopharmaceutical is a liquid, the volume;
 - (8) If the radiopharmaceutical is a solid, the number of capsules or weight contained therein;

- (9) If the radiopharmaceutical is a gas, the number of ampules, vials, or syringes contained therein;
- (10) The name, address and telephone number of the nuclear pharmacy dispensing the radiopharmaceutical;
- (11) The prescription or lot number; and
- (12) The name of the pharmaceutical.
- (b) No radiopharmaceutical may be dispensed unless a tamperevident seal is applied and a label is affixed to the delivery container of each dose bearing the following information:
 - (1) The standard radiation symbol.
 - (2) The words "Caution Radioactive Material."
 - (3) The radionuclide and chemical form.
 - (4) The volume if in liquid form.
 - (5) The requested activity and the calibration date and time.
 - (6) The prescription number.
 - (7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing. Where the patient's name is not available at the time of dispensing for diagnostic dosing, a seventy-two-hour exemption is allowed to obtain the name of the patient. No later than seventy-two hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in a readily retrievable manner and must be retained for a period of three years.
 - (8) The name and address of the nuclear pharmacy.
 - (9) The name of the end authorized user, must also be a prescriber.
 - (10) The lot number of the preparation.

Authority G.S. 90-85.6; 90-85.34.

21 NCAC 46 .2706 PROHIBITIONS

- (a) No person shall utilize unit-dose transport containers for radioactive dosages without an effective mechanism to avoid contamination of the transport container with blood or other biohazardous substances.
- (b) No person shall re-use a unit-dose transport container that has been contaminated with blood or other biohazardous substances. Any unit-dose transport container that is returned with the tamper-evident seal broken and the unit-dose syringe included must be considered to be contaminated.

Authority G.S. 90-85.6; 90-85.34.

SECTION .3300 – REGISTRATION OF A PHARMACY TECHNICIAN

21 NCAC 46 .3301 REGISTRATION

(a) Following initial registration with the Board, registration of a pharmacy technician shall be renewed annually and shall expire on December 31. It shall be unlawful to work as a pharmacy technician more than 60 days after expiration of the

- registration without renewing the registration. <u>An expired registration more than 60 days after its expiration may be renewed upon written request and upon payment of the registration fee and a data processing fee of eleven dollars (\$11.00).</u>
- (b) The current registration of a pharmacy technician shall be readily available for inspection by agents of the Board.
- (c) The training program described in G.S. 90-85.15A(b) is not required for students enrolled in a community college pharmacy technician program.
- (d) Volunteer pharmacy technicians providing services at a facility which has a pharmacy permit designated as a free clinic shall complete the training program described in G.S. 90-85.15A(b) but need not register with the Board.

Authority G.S. 90-85.6; 90-85.15A.

Note from the Codifier: The rules published in this Section of the NC Register are temporary rules reviewed and approved by the Rules Review Commission (RRC) and have been delivered to the Codifier of Rules for entry into the North Carolina Administrative Code. A temporary rule expires on the 270th day from publication in the Register unless the agency submits the permanent rule to the Rules Review Commission by the 270th day.

This section of the Register may also include, from time to time, a listing of temporary rules that have expired. See G.S. 150B-21.1 and 26 NCAC 02C .0500 for adoption and filing requirements.

TITLE 10A – DEPARTMENT OF HEALTH AND HUMAN SERVICES

Rule-making Agency: Division of Medical Assistance

Rule Citation: 10A NCAC 22G .0102-.0110

Effective Date: August 3, 2004

Date Approved by the Rules Review Commission: July 22,

2004

Reason for Action: House Bill 397 of the 2003 General Assembly directed the Department of Health and Human Services to implement provider assessment, thereby precipitating changes to the North Carolina Administrative Code (NCAC). These proposed changes are reflected in these Rules. The Centers for Medicare and Medicaid Services (CMS) has approved North Carolina for a new case mixed adjusted Resource Utilization Group (RUG) based reimbursement system for nursing facilities. With CMS's approval of a change to the State Medicaid Plan, effective October 1, 2003 North Carolina reimburses based on a case-mix system that combines the 34 individual RUG groupings into a single facility "nursing" level of care rate.

CHAPTER 22 – MEDICAL ASSISTANCE ELIGIBILITY

SUBCHAPTER 22G - REIMBURSEMENT PLANS

SECTION .0100 – REIMBURSEMENT FOR NURSING FACILITY SERVICES

10A NCAC 22G .0102 RATE SETTING METHODS

- (a) A rate for nursing facility care shall be determined quarterly for each facility to be effective for dates of service for a three month period beginning the first day of each calendar quarter. Rates shall be derived from either desk or field audited cost reports for a base year period to be selected by the state. For rates effective October 1, 2003, the FY01 cost reports shall be used as the base year period. Cost reports shall be filed and audited under provisions set forth in 10A NCAC 22G .0104. (b) Each prospective rate consists of two components: a direct care rate and an indirect rate computed and applied as follows:
 - (1) The direct care rate shall be that portion of the Medicaid daily rate that shall be attributable to:
 - (A) Case-mix adjusted costs defined as registered nurse (RN), licensed practical nurse (LPN) and nurse aide salaries and wages; a direct allocation

- or proportionate allocation of allowable payroll taxes and employee benefits; and the direct allowable cost of contracted services for RN, LPN and nurse aide staff from outside staffing companies.
- (B) Non-case-mix adjusted costs defined as nursing supplies, dietary or food service, patient activities, social services, a direct allocation or proportionate allocation of allowable payroll taxes and employee benefits, and Medicaid cost of direct ancillary services.
- (2) Each facility's direct care rate shall be determined as follows:
 - The per diem case-mix adjusted cost shall be determined by dividing the facility's case-mix adjusted base year cost by the facility's total base year days. inpatient This case-mix adjusted base year cost per diem shall be trended forward using the index factor set forth in Paragraph (e) of this Rule. A per diem neutralized case-mix adjusted cost shall be then calculated by dividing each facility's case-mix adjusted per diem cost by the facility cost report period casemix index. The facility cost report period case-mix index shall be the resident-weighted average quarterly facility-wide average casemix indices, carried to four decimal places. The quarters used in this average shall be the quarters that most closely coincide with the facility's base year cost reporting period. Example: An October 1, 2000 - September 2001 cost report period would use the facility-wide average case-mix indices for quarters ending December 31, 2000, March 31, 2001, June 30, 2001, and September 30, 2001.
 - (B) The per diem non-case-mix adjusted cost shall be determined by dividing the facility's non-case-mix adjusted base year cost, excluding the Medicaid cost of direct ancillary services, by the facility's total base

- year inpatient days plus the facility's Medicaid cost of direct ancillary services base year cost divided by the facility's total base year Medicaid resident days. This non-case-mix adjusted base year cost per diem shall be trended forward using the index factor set forth in Paragraph (e) of this Rule.
- (C) The base year per diem neutralized case-mix adjusted cost and the base year per diem non-case-mix adjusted cost shall be summed for each nursing facility. Each facility's base year per diem result shall be arrayed from low to high and the Medicaid-day-weighted median cost shall be determined. Also for each facility, the percentage that each of these components represents of the total shall be determined.
- (D) The statewide direct care ceiling shall be established at 110 percent of the base year neutralized case-mix adjusted and non-case mix adjusted Medicaid-day-weighted median cost.
- (E) For each nursing facility, the statewide direct care ceiling shall be apportioned between the per diem case-mix adjusted component and the per diem non-case-mix adjusted component using the facility-specific percentages determined in Part (b)(2)(C) of this Rule.
- (F) On a quarterly basis, each facility's direct care rate shall be adjusted to account for changes in its Medicaid average case-mix index. The facility's direct care rate shall be determined as the lesser of the facility's specific case-mix adjusted component of the statewide ceiling times the facility's Medicaid average case-mix index, plus each facility's specific non-case mix adjusted component of the statewide ceiling; or the facility's per diem neutralized case-mix adjusted cost times the Medicaid average casemix index, plus the facility's per diem non-case-mix adjusted cost. applicable an incentive allowance shall be included as provided below. Effective October 1, 2003, the incentive allowance shall be equal to 50% times the difference (if greater than zero) of the facility-specific case-mix component as set out above. The program will be rebased using full price-based methodology. The

- Division of Medical Assistance may negotiate direct rates that exceed the facility's specific direct care ceiling for ventilator dependent and head injury patients. Payment of such special direct care rates shall be made only after specific prior approval of the Division of Medicaid Assistance.
- (G) For rates effective October 1, 2003, the Medicaid average case-mix index calculated as of March 31, 2003 shall be used to adjust the case-mix adjusted component of the statewide direct care ceiling. For rates effective January 1, 2004 and thereafter, the prior quarters Medicaid average casemix index shall be used to adjust the case-mix adjusted component of the statewide direct care ceiling. Example: January 1, 2004 rate shall use the Medicaid average case-mix index calculated as of September 30, 2003.
- (H) The statewide direct care ceiling shall be adjusted annually using the index factor set forth in Paragraph (e) of this Rule. The facility's base year per diem neutralized case-mix adjusted cost plus the facility's base year per diem non-case-mix adjusted cost shall be adjusted annually using the index factor set forth in Paragraph (e) of this Rule.
- (3) The indirect rate shall be intended to cover the following costs of an efficiently and economically operated facility:
 - (A) Administrative and General;
 - (B) Laundry and Linen;
 - (C) Housekeeping;
 - (D) Operation of Plant and Maintenance/Non Capital;
 - (E) Capital Lease; and
 - (F) Medical Cost of Indirect Ancillary Services.
- (4) Effective for dates of service beginning October 1, 2003, the indirect rate shall be standard for all nursing facilities. Each facility's per diem indirect cost shall be the sum of:
 - (A) the facility's indirect base year cost, excluding the Medicaid cost of indirect ancillary services, divided by the facility's total base year inpatient days plus; and
 - (B) the facility's Medicaid cost of indirect ancillary services base year cost divided by the facility's total base year Medicaid resident days.

The base year per diem indirect cost, excluding property ownership and use and mortgage interest shall be trended forward using the index factor set forth in Paragraph (e) of this Rule. Each facility's base year per diem indirect cost shall be arrayed from low to high and the Medicaid-day-weighted median cost shall be determined. The indirect rate shall be established at 100 percent of the Medicaid-day-weighted median cost. The indirect rate shall be adjusted annually by the index factor set forth in Paragraph (e) of this Rule.

- (c) Nursing facility assessments. An adjustment to the nursing facility payment rate calculated in accordance with Paragraph (b) of this Rule shall be established, effective October 1, 2003, to reimburse Medicaid participating nursing facilities for the provider's assessment costs that shall be incurred for the care of North Carolina Medicaid residents. No adjustment shall be made for the provider's assessment costs that shall be incurred for the care of privately paying residents or others who shall be not Medicaid eligible.
- (d) Return on Equity. Effective October 1, 2003, the nursing facility payment rate calculated in accordance with Paragraph (b) of this Rule shall be adjusted to include a return on equity capital add-on for those proprietary providers who received a FY01 return on equity capital payment. The return on equity capital add-on shall be equal to the facility's total FY01 return on equity capital payment divided by the facility's base year total Medicaid resident days.
- (e) Index factor. The index factor shall be based on the Skilled Nursing Facility Market Basket without Capital Index published by Global Insight using the most current quarterly publication available annually as of August 1. The index factor shall not exceed that approved by the North Carolina General Assembly. If necessary, the Division of Medical Assistance shall adjust the annual index factor or rates in order to prevent payment rates from exceeding upper payment limits established by Federal Regulations.
- (f) New Facilities and Transfer of Ownership of Existing Facilities
 - (1) New facilities shall be those entities whose beds have not previously been certified to participate or otherwise participated in the Medicaid program immediately prior to the operation of the new owner. A new facility's rate shall be determined as follows and shall continue to be reimbursed under this Section until the incentive allowance percentage referenced in Part (b)(2)(F) of this Rule shall be equal to 100%:
 - (A) The direct care rate for new facilities shall be equal to the statewide Medicaid day-weighted average direct care rate that shall be calculated effective on the first day of each calendar quarter. After the second full calendar quarter of operation, the statewide Medicaid

- day-weighted average direct care rate in effect for the facility shall be adjusted to reflect the facility's Medicaid acuity and the facility's direct care rate shall be calculated as the sum of 65 percent of the statewide day-weighted average Medicaid direct care rate multiplied by the ratio of the facility's Medicaid average case-mix index (numerator) to the statewide Medicaid day-weighted average Medicaid case-mix index (denominator) and the statewide Medicaid day-weighted average direct care rate times 35%.
- (B) The indirect rate for a new facility shall be equal to the standard indirect rate in effect at the time the facility shall be enrolled in the Medicaid Program. The indirect rate shall be adjusted annually by the index factor set forth in Paragraph (e) of this Rule.
- (C) A new facility's rate shall include also the nursing assessment adjustment calculated in accordance with Paragraph (c) of this Rule.
- Transfer of ownership of existing facilities. (2) Transfer of ownership means, reimbursement purposes, a change in the majority ownership that does not involve related parties or related entities including, but not limited to, corporations, partnerships and limited liability companies. Majority ownership shall be defined as an individual or entity that owns more than 50 percent of the entity, which shall be the subject of the transaction. The following applies to the transfer of ownership of a nursing facility:
 - (A) For any facility that transfers ownership, the new owner shall receive a per diem rate equal to the previous owner's per diem rate less any return on equity adjustment received by the previous owner, rate adjusted quarterly to account for changes in its Medicaid average casemix index. The old provider's base year cost report shall become the new facility's base year cost report until the new owner has a cost report included in a base year rate setting.
 - (B) Regardless of changes in control or ownership for any facility certified for participation in the Medicaid program, the Division shall issue payments to the facility identified in the current Medicaid participation agreement. Regardless of changes in control of ownership for any facility

certified for participation in Medicaid, the Division shall recover from that entity liabilities, sanctions and penalties pertaining to the Medicaid program, regardless of when the services were rendered.

- (g) Each out-of-state provider shall be reimbursed at the lower of the appropriate North Carolina statewide Medicaid day-weighted average direct care plus the indirect rate or the provider's payment rate as established by the state in which the provider shall be located. For patients with special needs who must be placed in specialized out-of-state facilities, a payment rate that exceeds the North Carolina statewide Medicaid day-weighted average direct care plus the indirect rate may be negotiated. A facility's negotiated rate for specialized services shall be based on budget projections of revenues, allowable costs, patient days, staffing and wages, at a level no greater than the facility's specific projected cost, and subject to review.
- (h) Specialized Service Rates:
 - (1) Head Injury Intensive Rehabilitation Services.
 - A single all-inclusive prospective per diem rate combining both the direct and indirect cost components may be negotiated for nursing facilities that specialize in providing intensive rehabilitation services for head-injured patients. The rate may exceed the maximum rate applicable to other Nursing Facility services. A facility must specialize to the extent of staffing at least 50 percent of its Nursing Facility licensed beds for intensive head-injury rehabilitation services. The facility must also be accredited by the Commission for the Accreditation of Rehabilitation Facilities (CARF).
 - (B) A facility's initial rate shall be negotiated based on budget projections of revenues, allowable costs, patient days, staffing and wages, at a level no greater than the facility's specific projected cost, and subject to review upon completion of an audited full year cost report. The negotiated rate shall not be less than the North Carolina statewide Medicaid day-weighted average direct care plus the indirect rate. A complete description of the facility's medical program must also be provided. Rates in subsequent years shall be determined by applying the index factor as set forth in Paragraph (e) of this Rule average annual skilled nursing adjustment factors to the rate in the previous year, unless either the provider or the State requests a

- renegotiation of the rate within 60 days of the rate notice.
- (C) Cost reports for this service must be filed in accordance with the rules in 10A NCAC 22G .0104, but there shall not be cost settlements for any differences between cost payments. The negotiated rate shall be considered to provide payment for all financial considerations and shall include return or equity adjustment as defined in this Rule. The negotiated rate shall be paid to the facility for services provided to head injured patients only. The per diem payment rate for non-head injured patients shall be the rate calculated in accordance with Paragraphs (b)-(e) of this Rule.
- (2) Ventilator Services.
 - (A) Ventilator services approved for nursing facilities providing intensive services for ventilator dependent patients shall be reimbursed at higher direct rates as described in Subparagraph (b)(2)(A) of this Rule.
 - A facility's initial direct rate shall be (B) negotiated based on budget projections of revenues, allowable costs, patient days, staffing and wages, at a level no greater than the facility's specific projected cost, and subject to review upon completion of an audited full year cost report. The negotiated rate shall not be less than the North Carolina statewide Medicaid day-weighted average direct care plus the indirect rate. Rates in subsequent years shall be determined by applying the index factor as set forth in 10A NCAC 22G .0102(e) to the negotiated rate in the previous year, unless either the provider or the State requests a renegotiation of the rate within sixty days (60) of the rate notice.
 - (C) Cost reports for this service shall be filed in accordance with 10A NCAC 22G .0104 but there shall not be settlements for any difference between cost and payments.
 - (D) A single all-inclusive prospective per diem rate combining both the direct and indirect cost components may be negotiated for nursing facilities that specialize in providing intensive services for ventilator-dependent patients. The negotiated rate shall be considered to provide payment for all

financial considerations and shall not include the return on equity adjustment as defined in this Rule. The negotiated rate shall be paid to the facility for services provided to ventilator patients only. The per diem payment rate for non-ventilator patients shall be the rate calculated in accordance with Paragraphs (b)-(e) of this Rule.

- (i) Religious Dietary Considerations.
 - (1) A standard amount may be added to a nursing facility's rate for special dietary need for religious reasons.
 - (2) Facilities must apply to receive this special payment consideration. In applying, facilities must document the reasons for special dietary consideration for religious reasons and must submit documentation for the increased dietary costs for religious reasons. Facilities must apply for this special benefit each time rates shall be determined from a new database. Fifty or more percent of the patients in total licensed beds must require religious dietary consideration in order for the facility to qualify for this special dietary rate add-on.
 - (3) The special dietary add-on may not exceed more than 140% of the base year neutralized case-mix adjusted and non-case-mix adjusted Medicaid day-weighted median cost determined under 10A NCAC 22G .0102(b)(2)(D) and adjusted for inflation each year until a new database shall be used to determine rates.

History Note: Authority G.S. 108A-25(b); 108A-54;

108A-55; 29 C.F.R. 1910, Subpart Z; 42 C.F.R. 447, Subpart C; S.L. 1991, c. 689, s. 95;

Eff. January 1, 1978;

Temporary Amendment Eff. October 1, 1984 for a Period of 120 Days to Expire on January 28, 1985;

Temporary Amendment Eff. October 1, 1991 for a Period of 180 Days to Expire on March 31, 1992;

Amended Eff. April 1, 1992;

Temporary Amendment Eff. July 1, 1992 for a Period of 180

Days to Expire on December 31, 1992;

Amended Eff. May 1, 1995; February 1, 1993; January 1, 1993;

Temporary Amendment Eff. January 22, 1998;

Amended Eff. April 1, 1999;

Temporary Amendment Eff. November 9, 2001;

Temporary Amendment Expired August 30, 2002;

Amended Eff. April 1, 2003;

Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0103 REASONABLE AND NON-ALLOWABLE COSTS

(a) Providers have a responsibility to operate economically and efficiently so that their costs are reasonable. Providers are

required to provide services at the lowest possible costs in compliance with Federal and State laws, regulations for licensing and certification, and standards for quality of care and patients' safety. Providers are also responsible for the financial actions of their agents (e.g., management companies) in this regard.

- (b) The state may publish guidelines to define reasonable costs in certain areas after study of industry-wide cost conditions.
- (c) The following costs are considered non-allowable facility costs because they are not related to patient care or are specifically disallowed under the North Carolina State Plan:
 - (1) bad debts;
 - (2) advertising--except personnel want ads, and one line yellow page (indicating facility address);
 - (3) life insurance (except for employee group plans);
 - (4) interest paid to a related party;
 - (5) contributions, including political or church-related, charity and courtesy allowances;
 - (6) prescription drugs and insulin (available to recipients under State Medicaid Drug Program);
 - (7) vending machine expenses;
 - (8) personal grooming other than haircuts, shampooing (basic hair care services) and nail trimming performed by either facility staff or barbers/beauticians. The facility may elect the means of service delivery. The costs of services beyond those provided by the nursing facility, are the responsibility of the patient;
 - (9) state or federal corporate income taxes, plus any penalties and interest;
 - (10) telephone, television, or radio for personal use of patient;
 - (11) income taxes, plus any penalties and interest;
 - (12) dental expenses--except for consultant fees as required by law;
 - (13) farm equipment and other expenses;
 - (14) retainers, unless itemized services of equal value have been rendered;
 - (15) physicians fees for other than medical directors or medical consultants as required by law:
 - (16) country club dues;
 - (17) sitter services or private duty nurses;
 - (18) fines or penalties;
 - (19) guest meals;
 - (20) morgue boxes;
 - (21) leave days--except therapeutic leave;
 - (22) personal clothing;
 - (23) ancillary costs that are billable to Medicare or other third party payors.
- (d) For those non-allowable expenses which generate income, such as prescription drugs, vending machines, hair care (other than basic care), etc., expense shall be identified as a non-reimbursable cost center, where determinable. If the provider cannot determine the actual amount of expense which is

to be identified, then the income which was generated must be offset in full to the appropriate cost center if the income reasonably covers the cost incurred. If income generated does not reasonably cover the cost incurred, an adjustment must be made to recognize a reasonable amount of non-reimbursable cost.

(e) For combination facilities (e.g. Nursing/Adult Care Home), providers must ensure that salary and wage expense coded or allocated to each area considers minimum staffing requirements (nursing hours per patient day or census statistics as appropriate).

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; S.L. 1985, c. 479, s. 86; 42 C.F.R. 447, Subpart C; Eff. January 1, 1978; Temporary Amendment Eff. October 1, 1984 for a Period of 120 Days to Expire on January 28, 1985; Amended Eff. January 4, 1993; October 1, 1991; November 1, 1988; January 28, 1985; Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0104 COST REPORTING: AUDITING

- (a) Each facility that receives payments from the North Carolina Medicaid Program must prepare and submit an annual report of its costs and other financial information to include; the facility's original working trial balance, year end adjusting journal entries, and the facility's daily midnight census records for the cost reporting period. The report must include costs from the fiscal period beginning on October 1 and ending on September 30 and must be submitted to the state on or before the December 31 that immediately follows the September 30 year end. A new provider must submit a report for the period beginning with the date of certification and ending on September 30. Hospital based nursing facilities with a fiscal year ending other than September 30 and State operated facilities with a June fiscal year ending must file their cost reports within 150 days after their fiscal year ends. Facilities that fail to file their cost reports by the due date are subject to payment suspension until the reports are filed. The Division of Medical Assistance may extend the deadline 30 days for filing the report if, in its view, good cause exists for the delay. A good cause is an action that is uncontrollable by the provider.
- (b) Cost report format. The cost report must be submitted on forms provided by the Division of Medical Assistance. The account structure for the report is based on the chart of accounts published by the American Healthcare Association in 1979 but amended or modified to the extent necessary to meet the requirements of this plan. The Division of Medical Assistance shall make one copy of the cost report format with detailed instructions and guidance available to each facility (combination facilities receive only one) on or before September 1 of the reporting year for which the report is to be filed.
- (c) Cost finding and allocation. Costs must be reported in the cost report in accordance with the following rules and in the order of priority stated.
 - (1) Costs must be reported in accordance with the specific provisions of this plan as set forth in this Rule.

- (2) Costs must be reported in conformance with the Medicare Provider Reimbursement Manual, HCFA 15.
- (3) Costs must be reported in conformance with Generally Accepted Accounting Principles.
- (d) A provider may request clarification in writing from the state if there is uncertainty about the proper cost center classification of any particular expense item. Clarifications may be made prior to the beginning of each cost reporting period. In no case, however, shall any clarifications be applied retroactively.
 - (1) Nursing Cost Center includes the cost of nursing staff, medical supplies, and related operating expenses needed to provide nursing care to patients, including medical records (including forms), the Medical Director and the Pharmacy Consultant. The amount of nursing time provided to each patient must be recorded in order to allocate nursing cost between reimbursable and non-reimbursable cost centers.

The Division of Medical Assistance shall make available a non all inclusive list of items which may be reported as direct patient care equipment, consistent with the provisions of this Rule. This list may be prospectively modified by the Division of Medical Assistance at any time, based on the preponderance of evidence. Items reported as direct patient care equipment which are not on this list are subject to a case by case review during any audit conducted under Paragraph (e) of this Rule. Providers must demonstrate by a preponderance of evidence that such items meet the definition of direct patient care equipment as stated in this Rule. Providers are required to exercise the prudent buyer principle as set out in HCFA 15 when procuring direct patient care equipment. This provision is applicable to lease or depreciation expense incurred on or after October 1, 1996 regardless of when the equipment was initially leased or acquired. Direct patient care equipment maintenance and repair costs shall be reported in the Operation of Plant and Maintenance Cost Center. All other costs associated with direct patient care equipment shall be reported in the cost centers that would be appropriate if the costs were associated with other equipment.

- (2) Dietary Cost Center includes the cost of staff, raw food, and supplies needed to prepare and deliver food to patients.
- (3) Laundry and Linen Cost Center includes the cost of staff, bed linens (replacement mattresses and related operating expenses needed to launder facility-provided items).

- (4) Housekeeping Cost Center includes the cost of staff and supplies needed to keep the facility clean.
- (5) Patient Activities Cost Center includes the cost of staff, supplies, and related operating expenses needed to provide appropriate diversionary activities for patients.
- (6) Social Services includes the cost of social workers and related operating expenses needed to provide necessary social services to patients.
- (7) Ancillary Cost Center includes the cost of all therapy services covered by the Medicaid program and billable medical supplies. Providers must bill Medicare Part B for those ancillary services covered under the Medicare Part B program. Ancillary cost centers Radiology, Laboratory, Physical include: Therapy, Occupational Therapy, Speech Therapy, Oxygen Therapy, Intravenous Fluids, Billable Medical Supplies, Parenteral/Enteral Therapy and life sustaining equipment, such as oxygen concentrators, respirators, ventilators and other specifically approved equipment. Effective October 1, 1996, air fluidized beds (e.g. Clinitron beds), low air loss mattresses or beds and alternating pressure mattresses may be recorded in the life sustaining equipment cost center. program is applicable to lease or depreciation expense incurred on or after October 1, 1996 regardless of when the equipment was initially leased or acquired. Effective October 1, 1994, a separate ancillary cost center shall be established to include costs associated with medically related transportation for facility Medically related transportation residents. costs include the costs of vehicles leased or owned by the facility, payroll costs associated with transporting residents and payments to third parties for providing these services.
- Administrative and General Cost Center (8) includes all costs needed to administer the facility including the staff costs for the administrator, assistants, billing and secretarial personnel, personnel director and pastoral expenses. It includes the costs of copy machines, dues and subscriptions, transportation, income taxes, legal and accounting fees, start-up, and other administrative costs as set forth in the Chart of Accounts. Interest expense other than that stemming from mortgages or loans to acquire physical plant items shall be reported here.
- (9) Capital / Lease:
 - (A) This cost center includes all allowable costs related to the use of the physical assets including building, fixed equipment and movable

equipment, that are required to deliver patient care, except for automobiles and the special equipment, specified as Subparagraphs (d)(1) or (d)(7) of this Rule. Except for automobiles and the special equipment noted Subparagraphs (d)(1) and (d)(7), it includes the

lease expense for all physical assets; depreciation of assets utilizing the straight line method, per AHA guidelines; and interest expense of asset related liabilities, (e.g. mortgage expense).

- In establishing the allowable cost for (B) depreciation and for interest on capital indebtedness, with respect to an asset which has undergone a change of ownership, the valuation of the asset shall be the lesser of allowable acquisition cost less accumulated depreciation to the first owner of record on or after July 18, 1984 who received Medicaid payments for said asset or the acquisition cost to the new owner. Payment of rent by the Medicaid enrolled provider to the lessor of the facility shall constitute Medicaid payments under this Depreciation recapture shall not be performed at sale. The method for establishing the allowable related capital indebtedness shall be as follows. The allowable asset value shall be divided by the actual acquisition cost times the value of any related capital indebtedness. The result shall be the liability amount upon which interest may be recorded at the rate set forth in the debt instrument or such lower rate as the state may prove is reasonable.
- (10) Operation of Plant and Maintenance Cost /
 Non-Capital Cost Center includes all costs
 necessary to operate or maintain the
 functionality and appearance of the plant.
 These include: building and equipment,
 automobile depreciation and lease expense,
 property taxes and property insurance.
- (11) Equipment Expense. Equipment is defined as an item with a useful life of more than two years and a value greater than five thousand dollars (\$5000.00).

- (12) Training Expense. Training expense must be identified in the appropriate benefiting cost center.
- (13)The costs of training nurse aides in a competency and evaluation program approved by the Division of Facility Services, as set out in 42 CFR 483.151, 483.152 and 483.154, must be separately identified on the cost report and may include the cost of purchasing programs and equipment that have been approved by the State for training or testing. These costs shall be cost-settled during the desk or field audit and shall not be included in the direct care and indirect cost centers. A copy of the Code of Federal Regulations (CFR) may be obtained by contacting the Government Printing Office, Superintendent of Documents, Post Office Box 37194, Pittsburgh, Pennsylvania 15250-7954 or they mav accessed online www.gpoaccess.gov/cfr/retrieve/html.
- (14) Home Office Costs. Home office costs are generally charged to the Administrative and General Cost Centers. However, personnel costs which are direct patient care oriented may be allocated to "direct" patient care cost centers if time records are maintained to document the performance of direct patient care services. No home office overhead may be so allocated. The basis of this allocation among facilities participating in the North Carolina Medicaid program may be:
 - (A) specific time records of work performed at each facility, or
 - (B) patient days in each facility to which the costs apply relative to the total patient days in all the facilities to which the costs apply.
- (15)Management Fees. Management fees are charged to the Administrative and General However, a portion of a Cost Center. management fee may be allocated to a direct patient care cost center if time records are maintained to document the performance of direct patient care services. The amount so allocated may be equal only to the salary and fringe benefits of persons who are performing direct patient care services while employed by the management company. Records adequate to support these costs must be made available to staff of the Division of Medical Assistance. The basis of this allocation among facilities participating in the North Carolina Medicaid program may be:
 - (A) specific time records of work performed at each facility, or
 - (B) patient days in each facility to which the costs apply relative to the total

patient days in all the facilities to which the costs apply.

- (16)Related Organization Costs. A nursing facility shall demonstrate by convincing evidence to the satisfaction of the Division of Medical Assistance that the costs are reasonable. Reasonable costs of related organizations shall be identified in accordance with direct and indirect cost center categories as follows:
 - (A) Direct Cost:
 - i) Compensation of direct care staff such as nursing personnel (aides, orderlies, nurses), food service workers, housekeeping staff and other personnel who would normally be accounted for in a direct cost center.
 - (ii) Supplies and services that would normally be accounted for in a direct cost center.
 - Capital, rental, maintenance, (iii) supplies/repairs and utility costs (gas, water, electricity) for facilities that are not typically a part of a nursing facility. These facilities might include such warehouses, items as vehicles for delivery and offices which are totally dedicated or clearly exceed the number, size. complexity required for a normal nursing facility, its home office, or management company.
 - (iv) Compensation of all administrative staff who perform no duties which are related to the nursing facility or its home office and who are neither officers nor owners of the nursing facilities or its home office.
 - (B) Indirect Cost:
 - (i) Compensation of indirect staff such as housekeeping, laundry and linen, maintenance, and other personnel who would normally be accounted for in the indirect cost center.
 - (ii) Capital, rental, maintenance, supplies/repairs, and utility costs which are normally or frequently a part of a nursing

facility. This would include, for example, kitchen and laundry facilities.

- Except for salary and fringe (iii) benefits of Personnel. Accounting and Data Processing staff, home office costs which are allocated by methods approved by the Division Medical of Assistance are direct costs when the work performed is specific to the related organization that provides a direct care service or product the provider. determining if an allocation method is appropriate, a case-by-case review shall be made based on preponderance of evidence. proposed allocation method shall be denied if the review supports determination that the cost either associated exceeds the cost of comparable products or services that could he purchased elsewhere or was for services that were not related to direct patient care or services not covered by the North Carolina Medical Assistance program.
- (iv) Compensation of all administrative staff who perform any duties for the nursing facility or its home office.
- (v) All compensation of all officers and owners of the nursing facility or its home office, or parent corporation.

A related organization must file a Medicaid Cost Statement (DMA-4083) identifying its costs, adjustments to costs, allocation of costs, equity capital, adjustments to equity capital, and allocations of equity capital along with the nursing facilities cost report. A home office, or parent company, shall be recognized as a related organization. Auditable records to support these costs must be made available to staff of the Division of Medical Assistance and its designated contract auditors. Undocumented costs shall be disallowed. A nursing facility shall demonstrate by convincing evidence to the satisfaction of the Division of Medical Assistance that the criteria in the Medicare Provider Reimbursement Manual, Section 1010, have been met in order to be recognized as an exception to the related organization principle. When a related organization is recognized as an exception; reasonable charges

by the related organization to the nursing facility are recognized as allowable costs; receivable/payables from/to the nursing facility and related organization recognized as an exception are not adjusted from the nursing facility's balance sheet in computing equity capital.

- Auditing. All filed cost reports shall be desk audited and interim reimbursement settlements made in accordance with the provision of this plan. An Audit Adjustment Report shall be issued within one year of the date the cost report was filed or within one year of December 31 of the fiscal year to which the report applies, whichever is later. The state may elect to perform field audits on any filed cost reports within three years of the date of filing and issue a final Audit Adjustment Report on a time schedule that conforms to Federal law and regulation. If the state does not field audit a facility a final Audit Adjustment Report shall be issued based on the desk audited findings. The state may reopen and field audit any cost report after the final Audit Adjustment Report to comply with Federal law and regulation or to enforce laws and regulations prohibiting abuse of the Medicaid Program and particularly the provisions of this reimbursement plan.
- Providers who fail to fully and accurately Penalties. complete cost reports or who fail to furnish required documentation and disclosures for cost reports required under this Plan may be subject to penalties for non-compliance. Issues which are subject to penalties include, material miscoding of cost from Indirect to Direct cost centers or from Non-Reimbursable to Reimbursable cost centers, inaccurate identification of census data or ancillary charges by payor type, and failure to disclose related parties including those deemed non-related by exception. Errors in a filed cost report which result in an adjustment greater than one percent of a provider's reimbursable total cost per the filed cost report reported in the cost report shall be subject to penalty. Penalty shall be defined as the dollar value equal to five percent of the Medicaid percentage, as defined by occupancy, of the adjustment.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; 42 C.F.R. 447, Subpart C; Eff. January 1, 1978;

Amended Eff. March 22, 1978;

Emergency Amendment [(a), (h)] Eff. April 1, 1978 for a period of 120 days to expire on July 30, 1978;

Emergency Amendment [(a), (h)] Expired Eff. July 30, 1978;

Temporary Amendment Eff. October 1, 1984 for a period of 120 days to expire on January 28, 1985;

Amended Eff. August 1, 1998; June 1, 1995; January 4, 1993; October 1, 1991; December 1, 1988;

Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0105 CASE-MIX INDEX CALCULATION

(a) The Resource Utilization Groups-III (RUG-III) Version 5.12b, 34 group, index maximizer model shall be used as the resident classification system to determine all case-mix indices, using data from the minimum data set (MDS) submitted by each facility to the Division of Facility Services. The following case-mix indices shall be the basis for calculating facility average

case-mix indices to be used in determining the facility's direct care rate.

RUG	Case-Mix	RUG	Case-Mix	RUG	Case-Mix
Code	Index	Code	Index	Code	Index
SE3	2.08	CB2	1.13	PE2	0.97
SE2	1.70	CB1	1.01	PE1	0.96
SE1	1.45	CA2	1.02	PD2	0.91
RAD	1.68	CA1	0.92	PD1	0.83
RAC	1.41	IB2	0.89	PC2	0.82
RAB	1.28	IB1	0.82	PC1	0.80
RAA	1.06	IA2	0.74	PB2	0.66
SSC	1.40	IA1	0.64	PB1	0.61
SSB	1.29	BB2	0.86	PA2	0.60
SSA	1.25	BB1	0.80	PA1	0.57
CC2	1.39	BA2	0.72		
CC1	1.23	BA1	0.61		

- (b) Each resident in the facility on the last day of each quarter with a completed and submitted assessment shall be assigned a RUG-III 34 group calculated on the resident's most current assessment available on the last day of each calendar quarter. This RUG-III group shall be translated to the appropriate casemix index referenced in Paragraph (a) of this Rule. If the most current assessment available on the last day of the calendar quarter is a delinquent MDS then the RUG-III code assigned shall be a BC1-delinquent and the lowest case-mix index in Paragraph (a) of this Rule shall be applied. A delinquent MDS is defined as 121 days from the R2b date of the MDS assessment (completion date). From the individual resident case-mix index, two average case-mix indices for each Medicaid nursing facility shall be determined four times per year based on the last day of each calendar quarter.
- (c) The facility-wide average case-mix index is the simple average, carried to four decimal places, of all resident case-mix indices. The Medicaid average case-mix index is the simple average, carried to four decimal places, of all indices for residents where Medicaid or Medicaid pending is known to be the per diem payor source on the last day of the calendar quarter.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; S. L. 1985, c. 479, s. 86; 42 C.F.R. 447, Subpart C; Eff. January 1, 1978;

Amended Eff. March 25, 1980;

Temporary Amendment Eff. October 1, 1984 for a Period of 120 Days to Expire on January 28, 1985;

Amended Eff. March 1, 1994; April 1, 1988; January 28, 1985; Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0106 RECONSIDERATION REVIEWS

(a) As required by 42 CFR 447, Subpart C, providers may submit additional evidence for determination of reimbursement amounts pursuant to the Medicaid State Plan, Attachment 4.19-D, Section .0106, which is hereby incorporated by reference, with subsequent amendments and editions. Copies of Attachment 4.19-B, Section .0106 can be obtained from the Division of Medical Assistance at a cost of two cents (\$0.02) per page.

- (b) Indirect rates shall not be adjusted on reconsideration review.
- (c) Direct rates may be adjusted for the following reasons:
 - (1) to accommodate any changes in the minimum standards or minimum levels of resources required in the provision of patient care that are mandated by state or federal laws or regulation;
 - (2) to correct any adjustments or revisions to ensure that the payment rate is calculated in accordance with Rule .0102 of this Section.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; 150B-11; S.L. 1985, c. 479, s. 86;

42 C.F.R. 447, Subpart C;

Eff. January 1, 1978;

Temporary Amendment Eff. October 1, 1984 for a Period of 120 Days to Expire on January 28, 1985;

Amended Eff. January 4, 1993; November 1, 1991; May 1, 1990; June 1, 1989;

Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0107 PAYMENT ASSURANCE

- (a) The state shall pay each provider of nursing care services, who furnishes the services in accordance with the requirements of the State Plan and the participation agreement, the amount determined under the plan. In addition, Nursing Facilities must be enrolled in the Title XVIII Program. However, State-operated nursing facilities are not required to be enrolled in the Medicare program.
- (b) The payment methods and standards set forth herein are designed to enlist the participation of any provider who operates a facility both economically and efficiently. Participation in the program shall be limited to providers of service who accept, as payment in full, the amounts paid in accordance with the State Plan. This reimbursement plan is effective upon approval of the State Plan for Medical Assistance.
- (c) In all circumstances involving third party payment, Medicaid is the payor of last resort. No payment shall be made for a Medicaid recipient who is also eligible for Medicare, Part A, for the first 20 days of care rendered to skilled nursing

patients. Medicaid payments for co-insurance for such patients shall be made for the subsequent 21st through the 100th day of care. The Division of Medical Assistance shall pay an amount for each day of Medicare Part A inpatient co-insurance, the total of which shall equal the facility's Medicaid per diem rate less any Medicare Part A payment, but no more than the Medicare coinsurance amount. In the case of ancillary services providers shall:

- maintain detailed records or charges for all patients;
- (2) bill the appropriate Medicare Part B carrier for all services provided to Medicaid patients that may be covered under that program;
- (3) allocate an appropriate amount of ancillary costs, based on these charge records adjusted to reflect Medicare denials of coverage, to Medicare Part B in the annual cost report. For failure to comply with this requirement, the state may charge a penalty of up to five percent of a provider's indirect patient care rate for each day of care that is provided during the fiscal year in which the failure occurs. This penalty shall not be considered an allowable cost for cost reporting purposes.
- (4) properly bill Medicare or other third-party payors or have disallowance of any related cost claimed as Medicaid cost.
- (d) The state may withhold payments to providers under the following circumstances:
 - (1) Upon determination of any sum due the Medicaid Program or upon instruction from a legally authorized agent of the State or Federal Government the state may withhold sums to meet the obligations identified.
 - (2) The state may arrange repayment schedules within the limits set forth in federal regulations in lieu of withholding funds.
 - (3) The state may charge interest on overpayments from the date that the overpayment occurred.
 - (4) The state may withhold up to 20 percent per month of a provider's payment for failure to file a timely cost report and associated accounting records. These funds shall be released to the provider after a cost report is acceptably filed. The provider shall experience delayed payment while the check is routed to the state and split for the amount withheld.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; S.L. 1985, c. 479, s. 86; Section 95 of Chapter 689, 1991 Session Laws; 42 C.F.R. 447, Subpart C; Temporary Rule Eff. October 1, 1984 for a Period of 120 Days

Temporary Rule Eff. October 1, 1984 for a Period of 120 Days to Expire on January 28, 1985;

Eff. January 28, 1985;

Amended Eff. December 1, 1988;

Temporary Amendment Eff. August 1, 1991 For a Period of 180 Days to Expire on January 31, 1992;

Amended Eff. February 1, 1992; October 1, 1991; Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0108 REIMBURSEMENT METHODS FOR STATE-OPERATED FACILITIES

- (a) A certified State-operated nursing facility is reimbursed for the reasonable costs that are necessary to efficiently meet the needs of its patients and to comply with federal and state laws and regulations. The costs are determined in accordance with Rules .0103 and .0104 of this Section, except that annual cost reports are required for the fiscal year beginning on July 1 and ending on the following June 30 and must be submitted to the Division of Medical Assistance within 150 days after their fiscal year end. Payments shall be suspended if reports are not filed. The Division of Medical Assistance may extend the deadline for filing the report if the Division determines good cause. "Good cause" is an action uncontrollable by the provider. The Medicare principles for the reimbursement of skilled nursing facilities shall be utilized for the cost principles that are not specifically addressed in this Section.
- (b) A per diem rate based on the provider's estimated annual cost divided by patient days shall be used to make interim payments. A desk audit and a tentative settlement shall be performed on each annual cost report to determine the amount of Medicaid reasonable cost and the amount of interim payments received by the provider.
- (c) Any payments in excess of costs shall be refunded to the Division. Any costs in excess of payments shall be paid to the provider. An annual field audit shall be performed by a qualified independent auditor to determine the final settlement amounts.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; S.L. 1985, c. 479, s. 86; 42 C.F.R. 447, Subpart C; Eff. January 1, 1992;

Temporary Amendment Eff. August 3, 2004.

10A NCAC 22G .0109 PROVIDER ASSESSMENT

- (a) In accordance with 42 USC 1396b(w) and 42 CFR, Part 433, Subpart B; and consistent with the CMS Federal Waiver approved April 5, 2004 with an effective date of October 1, 2003 including subsequent amendments and revisions, a monthly nursing facility assessment based on all occupied nursing facility bed days of service is imposed on all nursing bed days in licensed nursing facilities, except:
 - (1) Any nursing facility bed day of service provided by a Continuing Care Retirement Community (CCRC), as defined by GS 58-64 and licensed by the North Carolina Department of Insurance;
 - (2) Any nursing facility bed day of service paid for under the Medicare program established under Title XVIII of the Social Security Act.

A copy of the Waiver may be obtained by contacting the Division of Medical Assistance, 2501 Mail Service Center, Raleigh, North Carolina 27699-2501, (919) 857-4016.

(b) Effective October 1, 2003, the assessment is payable monthly and due to the Department of Health and Human Services or designee of the Department within 15 days of the last

day of the reporting month. Facilities shall submit payment and an account of all actual patient days during the month. Failure to provide accurate and timely reporting of days and payment of assessment shall result in a 10% reduction in facility rates for Medicaid participating facilities and recoupment per the Department Cash Management Plan.

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; S.L. 2003-284, Sec. 10.28; CMS Waiver approved April 5, 2004; 42 CFR Part 433, Subpart B; Temporary Adoption Eff. August 3, 2004.

10A NCAC 22G .0110 DEFINITIONS

"Public nursing facility", as used in 10A NCAC 22G, means any nursing facility that is:

- (1) Owned or operated by the State or any department or instrumentality of the State or by county, city, hospital district, or hospital authority; or
- (2) Is operated by a nonprofit corporation or association, a majority of whose board of

- directors or trustees are appointed by the State or any department or instrumentality of the State or by the governing body of a county, city, hospital district, or hospital authority; or
- (3) Is operated by a hospital that is a "public hospital" under G.S. 159-39(a); or
- (4) Is operated by a hospital that has verified its status by certifying State, local, hospital district or authority governmental control on the most recent version of the Form CMS 1514; or
- (5) Is a facility to which the State or any department or instrumentality of the State or a city or a county makes current appropriations (other than appropriations for the cost of medical care to prisoners or indigents).

History Note: Authority G.S. 108A-25(b); 108A-54; 108A-55; 159-39(a);

Temporary Adoption Eff. August 3, 2004.

This Section contains information for the meeting of the Rules Review Commission on Thursday, August 19, 2004, 10:00 a.m. at 1307 Glenwood Avenue, Assembly Room, Raleigh, NC. Anyone wishing to submit written comment on any rule before the Commission should submit those comments by Friday, August 13, 2004 to the RRC staff, the agency, and the individual Commissioners. Specific instructions and addresses may be obtained from the Rules Review Commission at 919-733-2721. Anyone wishing to address the Commission should notify the RRC staff and the agency at least 24 hours prior to the meeting.

RULES REVIEW COMMISSION MEMBERS

Appointed by Senate

Jim R. Funderburke - 1st Vice Chair David Twiddy - 2nd Vice Chair Thomas Hilliard, III Robert Saunders Jeffrey P. Gray **Appointed by House** Jennie J. Hayman - Chairman

nnie J. Hayman - Chairmar Graham Bell Lee Settle Dana E. Simpson Dr. John Tart

RULES REVIEW COMMISSION MEETING DATES

August 19, 2004 September 16, 2004 October 21, 2004 November 18, 2004 December 16, 2004

RULES REVIEW COMMISSION JULY 22, 2004 MINUTES

The Rules Review Commission met on Thursday, July 22, 2004, in the Assembly Room of the Methodist Building, 1307 Glenwood Avenue, Raleigh, North Carolina. Commissioners present were: Graham Bell, Jim Funderburk, Thomas Hilliard, Robert Saunders, Lee Settle, Dana Simpson, and John Tart.

Staff members present were: Joseph DeLuca, Staff Director; Bobby Bryan, Rules Review Specialist; and Lisa Johnson, Administrative Assistant.

The following people attended:

Tony Arnold DENR

Lonnie ChristopherBanking CommissionHa NguyenBanking CommissionSteve DirksenBoard of Funeral Services

Cynthia Temoshenko Building Code

Walter James Department of Insurance
McNeil Chestnut Attorney/Banking Commission

Kerry Adams Department of Justice Ellie Sprenkel Department of Insurance

Bill Hale Attorney

Dana Sholes Office of Administrative Hearings
Julie Brincefield Office of Administrative Hearings

Sid Harrell DENR

Rondra McMillan

Sharon Stroud

Cynthia Moseley

Nadine Pfeiffer

Mercidee Benton

Department of Administration

Department of Administration

Department of Administration

DHHS/Division of Facility Services

DHHS/Division of Facility Services

Blue Ridge Environmental Defense League

Melissa Fiffer Blue Ridge Environmental Defense League

Craig Smith DHHS/DFS/CON

Preston Howard Manufacturers and Chemical Industry Council

Steve Wall DENR

Souk Rios Cosmetic Art Examiners
Gretchen Aycock Department of Administration

Thomas Allen DENR/DAQ

Lisa Martin NC Home Builders Association

David McLeod Agriculture
Dedra Alston DENR

Denise Stanford Attorney/Board of Pharmacy
Kris Horton DHHS/Division Medical Assistance

Sarah Meacham Attorney General's Office

APPROVAL OF MINUTES

The meeting was called to order at 10:00 a.m. with Commissioner Jim Funderburk presiding. Commissioner Funderburk asked for any discussion, comments, or corrections concerning the minutes of the June 17, 2004, meeting. The minutes were approved as written.

FOLLOW-UP MATTERS

1 NCAC 41B .0301; .0306; .0401; .0402; .0502; .0504: Department of Administration - The Commission approved the rewritten rules submitted by the agency.

2 NCAC 34 .0605: NC Structural Pest Control Committee – The Commission approved the rewritten rule submitted by the agency.

15A NCAC 02D .0543: Environmental Management Commission – The Commission returned this rule for failure to comply with the Administrative Procedures Act. This is based on the fact that the rule has a substantial economic impact as determined by the Office of State Budget and Management. However, the agency in its notice of text stated that the rule had no fiscal impact.

15A NCAC 02D .0902: Environmental Management Commission – The Commission approved the rewritten rules submitted by the agency.

15A NCAC 02D .1104: Environmental Management Commission – The Commission received at least ten letters requesting that this rule be subject to legislative review. The Commission approved this rule.

15A NCAC 02D .1904: Environmental Management Commission – The Commission approved the rewritten rule submitted by the agency.

15A NCAC 02Q .0706; .0714: Environmental Management Commission – The Commission received at least ten letters requesting that this rule be subject to legislative review. The Commission approved these rewritten rules.

- 21 NCAC 10 .0202: NC State Board of Chiropractic Examiners The Commission approved the rewritten rule submitted by the agency.
- 21 NCAC 34A .0102-.0104; .0117; .0118; .0122; .0123: NC Board of Funeral Services The Commission approved the rewritten rules submitted by the agency.
- 21 NCAC 34C .0103-.0105; .0302; .0303: NC Board of Funeral Services The Commission approved the rewritten rules submitted by the agency.

LOG OF FILINGS

19:04

Commissioner Funderburk presided over the review of the log of permanent rules and log of temporary rules and all rules were approved unanimously with the following exceptions:

1 NCAC 41C .0101-.0103: Department of Administration – The Commission objected to these rules. They are unnecessary. They neither require nor forbid any action on anyone's part. They do not allow something to take place that was previously forbidden. For the most part they simply repeat the statute.

1 NCAC 41C .0104: Department of Administration - The Commission objected to the rule based on lack of authority for the rule. In items (17) and (18) there is a requirement that a person be a licensed professional engineer or architect to be a "technical analyst" or to

perform a "technical analysis." There is no authority cited to require such a job qualification. It is unknown, for the purpose of this analysis, whether such work would be classified as the practice of engineering or architecture such that an occupational license would be required to perform the work. Even if it were, then it is the responsibility and authority of the licensing board to enforce that occupational license. There is no authority cited here for the Department of Administration to enforce either of those occupational licenses.

1 NCAC 41C .0201: Department of Administration - The Commission objected to the rule based on ambiguity. The first sentence of this rule provides that the eligibility within this rule is "in descending order of priority." There are two problems with this. The first problem is that it may be unclear whether the order is simply the two separate numbered classes listed in the rule and that order within those numbered classes does not affect priority. One would assume that it is only the numbered classes that are first and second priority and that there are no further ordering. But that is not stated and may be a source of confusion. However the more difficult problem is that neither this rule nor any other rule appears to set the standards for how the priority is applied. In other words do all the applicants in the first group get their loans (if they meet the qualifications) before any of the applicants in the second group, or are other standards at work also? The rules do not seem to set any standard for determining how the priority is to be applied. It is also unclear how a "local government organization" in item (2) can "translocate" to North Carolina. Presumably all local governments that this rule would apply to are already located within the state. Partly because of that lack of clarity, this part of the rule then becomes unclear in whether the emphasis of the rule is on the fact that some entity is "translocating" or whether the emphasis is on the fact that this item applies to planned construction only and not to a building already in existence, or both aspects together.

1 NCAC 41C .0202: Department of Administration - The Commission objected to the rule based on lack of authority and ambiguity. In (3) it is unclear what is meant by the apparent rule criteria "to keep interest rates low." It is unclear what is meant or required by this criteria and it is unclear what is the relationship between keeping interest rates low and the other part of this rule specifying a maximum total loan indebtedness. In item (4) it is unclear what constitutes or is meant by "proven reliable commercially available technologies." It is unclear what standards are to be used by the State Energy Office in "recognizing" such technologies. To the extent that such recognition is based on standards set outside rulemaking, there is no authority for that method of setting standards.

1 NCAC 41C .0209; .0302; .0303: Department of Administration - The Commission objected to these rules based on lack of authority. The Commission has objected to rule .0104 because the agency has not cited any authority to require that only certain licensed persons perform the "technical analysis" work. By requiring, in .0209(2), .0302(2), and .0303(4), that the final technical analysis report must include the "professional registration seal affixed" to the report, this rule continues that requirement. There is no authority cited for requiring the work to be done by certain licensed professionals. The agency does have the authority to require that it be sealed if it is prepared by one of those professionals or to require that the qualifications of the person preparing the report be listed. But that is not the same as requiring that a certain professional prepare it.

1 NCAC 41C .0301: Department of Administration - The Commission objected to the rule based on ambiguity. It is unclear who or what constitutes a "qualified third party technical analyst."

4 NCAC 03B .0103: NC Banking Commission – The Commission objected to this rule based on lack of authority. The last sentence in paragraph (b), lines 12 and 13, requires anyone making an oral presentation before the Banking Commission, including a presentation at public hearings, to "submit a written copy of the presentation" to the rulemaking coordinator. It does not seem that the Banking Commission has the authority to require that any oral comments made at a public hearing be reduced to writing. They certainly have not cited any. It seems to the RRC that the point of a public hearing is to give people the opportunity to appear before the rulemaker without having to reduce that appearance to writing. It would also appear to limit a person's oral comments to whatever was prepared in writing ahead of time. It is unclear how a person would be able to submit written comments contemporaneously with having just spoken them, if they varied from the written submission. The statutory authority cited includes the Administrative Procedure Act. That portion of the APA requires the rulemaker to "consider fully all written and oral comments received." [Emphasis supplied.] If they failed to consider oral comments because they were not accompanied by written ones, they would be violating this provision. The same would apply if they did not allow someone to speak because they did not have written copies of their comments.

11 NCAC 01 .0425: Department of Insurance – The Commission objected to the rule due to ambiguity. In (a), it is not clear what standards the hearing officer will use to determine "timeliness". The objection applies to existing language in the rule.

12 NCAC 07D .0903: NC Private Protective Services Board –The Commission objected to the rule due to lack of statutory authority. There is no authority cited to charge a new certified trainer a certification fee as well as an application fee. G.S. 74C-9(e)(9) and (10) authorize the fees. Item 9 allows the application fee of up to \$50. Item 10 allows a renewal or replacement fee of up to \$25. There does not appear to be authority to charge the second fee for a new certificate. This objection applies to existing language in the rule. 12 NCAC 07D .0909: NC Private Protective Services Board – The Commission objected to the rule due to lack of statutory authority and ambiguity. The formatting of (3)(f) makes it impossible to tell exactly what is required or allowed. Is the student performance requirement part of the principles of instruction requirement or in addition to it? Is possessing a certificate from the Criminal Justice Education and Training Standards Commission an alternative to the student performance requirement, the principles of instruction requirement or everything in (3) etc.? It cannot be told by reading the rule. In addition, it is not clear what standards the director will use in approving other training certification. There is also no authority cited for the Board to require additional training without any

kind of standards being in the rules. In (4), it is not clear who the licensee who must give a favorable recommendation is. It would appear to be anyone licensed by this Board, but that is not clear.

12 NCAC 07D .0910: NC Private Protective Services Board – The Commission objected to the rule due to ambiguity. In (2), it is not clear what other certification is acceptable.

15A NCAC 18D .0102: NC Water Treatment Facility Operators Certification Board – The Commission objected to the rule due to lack of necessity. This rules serves no purpose and is thus unnecessary. It merely says the statute creating the Board applies. The objection applies to existing language in the rule.

15A NCAC 18D .0105: NC Water Treatment Facility Operators Certification Board - This rule was withdrawn at the agency's request.

15A NCAC 18D .0201: NC Water Treatment Facility Operators Certification Board – The Commission objected to the rule due to ambiguity. Throughout this rule, there are references to schools and training "approved by the Board" but there do not appear to be any standards in the rules for the approval of schools or training. It is not clear what the approval standards are.

21 NCAC 14H .0107: Board of Cosmetic Art Examiners – The Commission objected to the rule due to ambiguity. It is not clear what constitutes an "adequate" supply of hot and cold water. It is also not clear who or what it must be "convenient" to. The objection applies to existing language in the rule.

COMMISSION PROCEDURES AND OTHER BUSINESS

Mr. DeLuca updated Commission members on lawsuits.

Mr. DeLuca also announced that the General Assembly transferred the Rules Review Commission to the Office of Administrative Hearings as of October 1, 2004.

The meeting adjourned at 12:03 p.m.

The next meeting of the Commission is Thursday, August 19, 2004, at 10:00 a.m.

Respectfully submitted, Lisa Johnson

> Commission Review/Administrative Rules Log of Filings June 22, 2004 through July 21, 2004

ENVIRONMENTAL MANAGEMENT COMMISSION

The rules in Chapter 2 are rules concerning environmental management and are promulgated by the Environmental Management Commission. The rules in Subchapter 2B pertain to surface water standards and monitoring including procedures for assignment of water quality standards (.0100); the standards and classification themselves (.0200); steam classification (.0300); effluent limitations (.0400); and monitoring and reporting requirements (.0500).

French Broad River Basin Amend/* 15A NCAC 02B .0304

COASTAL RESOURCES COMMISSION

The rules in Chapter 07 pertain to coastal Management and are promulgated by the Division of coastal Management or the Coastal Resources Commission. The rules in Subchapter 07H are the state guidelines for areas of environmental concern including introduction and general comments (.0100); the estuarine system (.0200); ocean hazard areas (.0300); public water supplies (.0400); natural and cultural resources areas (.0500); general permit for construction of bulkheads and the placement of riprap for shoreline protection in estuarine and public trust waters (.1100); piers, docks and boat houses in estuarine and public trust waters (.1200); boat ramps along estuarine shorelines and into estuarine and public trust waters (.1300); wooden groins in estuarine and

public trust waters (.1400); excavation within or connecting to existing canals, channels, basins, or ditches in estuarine waters, public trust waters, and estuarine shorelines AECs (.1500); aerial and subaqueous utility lines with attendant structures in coastal wetlands, estuarine waters, public trust waters and estuarine shorelines (.1600); emergency work requiring a CAMA and/or a dredge and fill permit (.1700); beach bulldozing landward of the mean high-water mark in the ocean hazard AEC (.1800); temporary structures within the estuarine and ocean hazard AECs (.1900); marsh enhancement breakwaters for shoreline protection in estuarine and public trust waters (.2100); general permits for construction of freestanding moorings in established waters and public trust areas (.2200); general permits for replacement of existing bridges and culverts in estuarine waters, estuarine shorelines, public trust areas and coastal wetlands (.2300); general permit for placement of riprap for wetland protection in estuarine and public trust waters (.2400); emergency general permits for conditions caused by hurricanes or tropical storms (.2500); and a general permit for construction of mitigation sites by the NC Ecosystem Enhancement Program or the NC Wetlands Restoration Program (.2600).

Purpose Adopt/*	15A NCAC 07H .2601
Approval Procedures Adopt/**	15A NCAC 07H .2602
Permit Fees Adopt/*	15A NCAC 07H .2603
General Conditions Adopt/*	15A NCAC 07H .2604
Specific Conditions Adopt/*	15A NCAC 07H .2605

STATE PERSONNEL COMMISSION

The rules in Subchapter 1C are personnel administration rules including general employment policies (.0200); personnel records and reports (.0300); appointment (.0400); work schedule (.0500); competitive service (.0600); and secondary employment (.0700).

Equal Employment Opportunity Amend/*	25	NCAC 01C .0202
Employment of Relatives Repeal/*	25	NCAC 01C .0203
Commitments and Position Vacancy Repeal/*	25	NCAC 01C .0204
Qualifications Repeal/*	25	NCAC 01C .0209
Information on Group Insurance Programs Repeal/*	25	NCAC 01C .0212
Information Sources Repeal/*	25	NCAC 01C .0213
Maintenance of Records Amend/*	25	NCAC 01C .0301
Maintenance of Records Open to Public Inspection Repeal/*	25	NCAC 01C .0302
Public Inspection Amend/*	25	NCAC 01C .0303
Confidential Information in Personnel Files Amend/*	25	NCAC 01C .0304
Records of Former Employees and Applicants for Employment Repeal/*	25	NCAC 01C .0305
Reports Repeal/*	25	NCAC 01C .0310
Permanent Appointment	25	NCAC 01C .0402

Amend/*			
Trainee Appointment Amend/*	NCAC (01C	.0403
Trainee Appointment Amend/*	NCAC (01C	.0403
Probationary Appointment Amend/*	NCAC (01C	.0404
Implementation Repeal/*	NCAC (01C	.0503
<u>Limitations</u> Repeal/*	NCAC (01C	.0504
Adverse Weather Conditions Repeal/*	NCAC (01C	.0506
Work Options Program Amend/*	NCAC (01C	.0509
Policy Amend/*	NCAC (01C	.0701
Agency Responsibility Amend/*	NCAC (01C	.0702
Employee Responsibility Adopt/*	NCAC (01C	.0703
Purpose Amend/*	NCAC (01C	.0801
Definitions of Terms Repeal/*	NCAC (01C	.0803
Office of State Personnel Responsibilities Amend/*	NCAC (01C	.0804
Resignation Amend/*	NCAC (01C	.1002
Unavailability When Leave is Exhausted Amend/*	NCAC (01C	.1007
Appointment Ended Amend/*	NCAC (01C	.1008
Separation Payment of Vacation Leave Amend/* 25 N	NCAC (01C	.1009

The rules in Subchapter 1E cover employee benefits including general leave provisions (.0100); vacation leave (.0200); sick leave (.0300); workers compensation leave (.0700); military leave (.0800); holidays (.0900); miscellaneous leave (.1000); other types of leave without pay (.1100); community involvement (.1200); the voluntary shared leave program (.1300); family and medical leave (.1400); and child involvement leave (.1500).

Types of Leave Amend/*	25	NCAC 01E .0102
Purpose and Uses Repeal/*	25	NCAC 01E .0201
Scheduling Leave Repeal/*	25	NCAC 01E .0202
Leave Credits Amend/*	25	NCAC 01E .0203
Maximum Accumulation Amend/*	25	NCAC 01E .0205
Scheduling and Advancement	25	NCAC 01E .0206

19:04

Amend/*		
<u>Leave Charges</u> Amend/*	25	NCAC 01E .0207
Amend/* <u>Leave Transferable</u> Amend/*	25	NCAC 01E .0208
Options During Leave Without Pay Repeal/*	25	NCAC 01E .0209
Leave Records Amend/*	25	NCAC 01E .0211
Special Leave Amend/*	25	NCAC 01E .0212
Accounting for Creditable Service Repeal/*	25	NCAC 01E .0216
Accounting for Creditable Service Repeal/*	25	NCAC 01E .0216
Sick Leave Credits Amend/*	25	NCAC 01E .0301
Separation Amend/*	25	NCAC 01E .0311
Retirement Credit Repeal/*	25	NCAC 01E .0313
Sick Leave Without Pay Amend/*	25	NCAC 01E .0314
<u>Leave Records</u> Amend/*	25	NCAC 01E .0315
Administration Amend/*	25	NCAC 01E .0705
Responsibility of Employee and Employer Repeal/*	25	NCAC 01E .0706
Use of Leave Amend/*	25	NCAC 01E .0707
Continuation of Benefits Repeal/*	25	NCAC 01E .0708
Return to Work Amend/*	25	NCAC 01E .0709
Periods of Entitlement for All Reserve Components Amend/*	25	NCAC 01E .0804
Religious Observance Amend/*	25	NCAC 01E .0902
Scheduling Holidays Repeal/*	25	NCAC 01E .0903
Time Allowed Off Repeal/*	25	NCAC 01E .0904
Workweeks Other Than Five Eight-Hour Days Amend/*	25	NCAC 01E .0909
Jury Duty Amend/*	25	NCAC 01E .1001
<u>Leave Employee Transfer</u> Amend/*	25	NCAC 01E .1004
<u>Leave with Pay for Time to Locate New Residence</u> Repeal/*	25	NCAC 01E .1007
Leave with Pay When Moving to New Residence	25	NCAC 01E .1008

19:04

Repeal/*		
Policy Amend/*	25	NCAC 01E .1101
Maximum Amount Amend/*	25	NCAC 01E .1102
Agency Responsibility Amend/*	25	NCAC 01E .1104
Retention of Benefits Amend/*	25	NCAC 01E .1105
Salary Increase Anniversary Date Repeal/*	25	NCAC 01E .1107
Retirement Status Repeal/*	25	NCAC 01E .1108
Extended Leave Without Pay Amend/*	25	NCAC 01E .1111
Short Leave Without Pay Amend/*	25	NCAC 01E .1112
Purpose Repeal/*	25	NCAC 01E .1301
Policy Amend/*	25	NCAC 01E .1302
Qualifying to Participate in Voluntary Shared Leave Program Amend/*	25	NCAC 01E .1304
Leave Accounting Procedures Amend/*	25	NCAC 01E .1306
Purpose and Scope Amend/*	25	NCAC 01E .1401
Eligible Employees Amend/*	25	NCAC 01E .1402
Definitions Repeal/*	25	NCAC 01E .1403
Leave Charges Amend/*	25	NCAC 01E .1404
Intermittent Leave or Reduced Work Schedule Repeal/*	25	NCAC 01E .1405
Agency Responsibility Amend/*	25	NCAC 01E .1406
Employee Responsibility Amend/*	25	NCAC 01E .1407
Certification Repeal/*	25	NCAC 01E .1408
Employment and Benefits Protection Repeal/*	25	NCAC 01E .1409
Interference with Rights Repeal/*	25	NCAC 01E .1410
Recordkeeping Requirements Repeal/*	25	NCAC 01E .1411
Purpose Amend/*	25	NCAC 01E .1601

The rules in Subchapter 1L are the State's equal employment opportunity rules including rules relating to equal employment

Special Provisions Relative to Handicap Adopt/*

25 NCAC 01L .0401

AGENDA RULES REVIEW COMMISSION August 19, 2004

Call to Order and Opening Remarks

Review of minutes of last meeting

Follow Up Matters

- A. Department of Administration 1 NCAC 41C .0101 -.0104; .0201; .0202; .0209; .0302; .0303 (DeLuca)
- B. N.C. Banking Commission 4 NCAC 3B .0103 (DeLuca)
- C. Department of Insurance 11 NCAC 1 .0425 (Bryan)
- D. N.C. Private Protective Services Board 12 NCAC 7D .0903; .0909; .0910 (Bryan)
- E. NC Water Treatment Facility Operators Certification Board 15A NCAC 18D .0201 (Bryan)
- F. Board of Cosmetic Art Examiners 21 NCAC 14H .0107 (Bryan)
- G. NC State Board of Community Colleges 23 NCAC 2D .0202 (DeLuca)
- H. State Personnel Commission 25 NCAC 1D .0518; .1402 (DeLuca)
- I. State Personnel Commission 25 NCAC 1I .2005 (DeLuca)

Review of Rules (Log Report #212)

Review of Temporary Rules (if any)

Commission Business

Next meeting: September 16, 2004

This Section contains the full text of some of the more significant Administrative Law Judge decisions along with an index to all recent contested cases decisions which are filed under North Carolina's Administrative Procedure Act. Copies of the decisions listed in the index and not published are available upon request for a minimal charge by contacting the Office of Administrative Hearings, (919) 733-2698. Also, the Contested Case Decisions are available on the Internet at http://www.ncoah.com/hearings.

OFFICE OF ADMINISTRATIVE HEARINGS

Chief Administrative Law Judge JULIAN MANN, III

Senior Administrative Law Judge FRED G. MORRISON JR.

ADMINISTRATIVE LAW JUDGES

Sammie Chess Jr. Beecher R. Gray Melissa Owens Lassiter James L. Conner, II Beryl E. Wade A. B. Elkins II

RULES DECLARED VOID

04 NCAC 02S .0212 CONSUMPTION: INTOXICATION BY PERMITTEE PROHIBITED

Pursuant to G.S. 150B-33(b)(9), Administrative Law Judge James L. Conner, II declared 04 NCAC 02S .0212(b) void as applied in NC Alcoholic Beverage Control Commission v. Midnight Sun Investments, Inc. t/a Tiki Cabaret (03 ABC 1732).

20 NCAC 02B .0508 FAILURE TO RESPOND

Pursuant to G.S. 150B-33(b)(9), Administrative Law Judge Melissa Owens Lassiter declared 20 NCAC 02B .0508 void as applied in Burton L. Russell v. Department of State Treasurer, Retirement Systems Division (03 DST 1715).

AGENCY	CASE NUMBER	<u>ALJ</u>	DATE OF DECISION	PUBLISHED DECISION REGISTER CITATION
ABC COMMISSION ABC Commission v. Richard Martin Falls, Jr., T/A Falls Quick Stop ABC Commission v. Red Lion Manestream, Inc., T/A Red Lion Manestream	04 ABC 0341 04 ABC 0695	Mann Wade	07/16/04 07/20/04	
<u>VICTIMS COMPENSATION</u> Angelique M. Jones on behalf of a juvenile victim, her son, Jaquial Jones v. Victims Compensation Commission	03 CPS 2353	Conner	07/12/04	
DEPARTMENT OF AGRICULTURE NC Spring Water Assoc, Inc., Wiley Fogleman (President) v. DOA, David McLeod and Table Rock Spring Water Co.	04 DAG 0110	Gray	07/21/04	
DEPARTMENT OF ADMINISTRATION Larry Yancey v. GACPD, DOA	04 DOA 0896	Morrison	07/28/04	
HEALTH AND HUMAN SERVICES Margaret Bollo v. DHHS, Broughton Hospital Walter Ray Nelson, Jr., Karen Marie Nelson v. DHHS Olufemi Augustine Ohome v. DHHS, Div. of Facility Services Charles Crawford Cox v. DHHS Bio-Medical Applications of North Carolina, Inc v. DHHS, Div of Facility Services, CON Section and Total Renal Care of NC, LLC Herbert Lee Henry v DHHS, Div. of Facility Services Lativia L. Gibbs v. DHHS, Div. of Child Development Rebecca Stephens Short v. DHHS, Div of Facility Services Pamela Narron (Legal Guardian for) Benjamin Chad Pierce v. DHHS, Div of Mental Health – DD-SA Mooresville Hospital Management Assoc, Inc d/b/a Lake Norman Reg. Medical Center v. DHHS, Div of Facility Services, CON Section and Novant Health, Inc. (Lessor) and Forsyth Memorial Hospital (Lessee) d/b/a Forsyth Medical Center Louvenia Jones, Sheryl Willie – General Power of Attorney v. DHHS, Div of Child Development	03 DHR 0444 03 DHR 0884 03 DHR 1062 03 DHR 1546 03 DHR 1553 03 DHR 1590 03 DHR 1746 03 DHR 1806 03 DHR 2377 03 DHR 2404	Gray Lassiter Lassiter Lassiter Chess Connor Smith Conner Conner	07/21/04 05/18/04 05/24/04 07/07/04 06/02/04 06/18/04 07/23/04 06/11/04 07/19/04 06/08/04	19:03 NCR 451
John Michael Thompson v. DHHS, DFS Alisa Hodges Yarborough v. DHHS, DFS	04 DHR 0046 04 DHR 0176	Lassiter Elkins	07/27/04 07/19/04	

LaDunna K. Brewington v. DHHS, Div of Medical Assistance				
Babanna it. Bie wington v. Biirib, Biv of Medical rissistance	04 DHR 0192	Mann	06/09/04	
Martha Williams, Kidtz Town v Div of Child Development	04 DHR 0200	Elkins	06/11/04	
Eula P. Street v. DHHS, DFS	04 DHR 0332	Elkins	07/14/04	
Donnell Williams v. Harnet County DSS	04 DHR 0334	Conner	06/28/04	
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Terry William Waddell v. Medicaid/NC Health Choice	04 DHR 0335	Mann	06/04/04	
Nathan E. Lang vs DHHS	04 DHR 0439	Conner	06/23/04	
Phyllis S. Weaver v. DHHS	04 DHR 0457	Conner	07/19/04	
Ray J. Bobbitt v. Nash County Dept. of Social Services	04 DHR 0529	Elkins	07/13/04	
Connie Watt Redice v. DHHS	04 DHR 0546	Lassiter	06/29/04	
	04 DHR 0602	Elkins	07/14/04	
Emelie Kashangura v. DHHS, DFS				
Sabrina Betts v. NC Health Personnel Registry	04 DHR 0644	Lassiter	06/02/04	
Tanisha Mitchell v. DHHS, Div. of Facility Services	04 DHR 0787	Mann	06/23/04	
Fox's Tot, Inc., Connie Fox v. DHHS	04 DHR 0881	Elkins	07/20/04	

A list of Child Support Decisions may be obtained by accessing the OAH We	bsite: www.ncoah	.com/decisions.		
DEPARTMENT OF JUSTICE Larry Mitchel Batton, Jr. v. Crimianl Justice Education & Training	03 DOJ 1067	Lassiter	06/15/04	
Standards Comission Steve A. Matthews v. Sheriff's Education & Traning Standards Commission	03 DOJ 1702	Conner	05/10/04	
Tony M. Evans and Kristopher D. Harris v. Criminal Justice Educ. & Trainin Standards Commission	g 03 DOJ 2354	Mann	07/19/04	
Tony M. Evans and Kristopher D. Harris v. Criminal Justice Educ. & Trainin Standards Commission	g 03 DOJ 2355	Mann	07/19/04	
Charles Robert Branham v. Criminal Justice Education & Training Standards Comission	03 DOJ 2431	Conner	06/22/04	
Bernard Cotton v. DOJ	04 DOJ 0063	Chess	06/03/04	
Jason Oneil Rice v. Sheriffs' Education & Training Standards Commission	04 DOJ 0318	Mann	06/24/04	
Guy Wesly Prevette v. Criminal Justice Educ. & Training Standards Comm.	04 DOJ 0511	Chess	07/08/04	
Connelly Allen Locklear v. Criminal Justice Educ. & Training Standards	04 DOJ 0514	Gray	07/15/04	
Commission			********	
Maureen Cleary Williams v. Sheriffs' Education & Training Standards Comm	04 DOJ 0829	Mann	07/28/04	
DEPARTMENT OF TREASURER				
Mary Pender v. DOT, Retirement Systems Division	04 DST 0027	Conner	07/23/04	
DEPARTMENT OF PUBLIC INSTRUCTION				
Alice Bins Rainey, Michele R Rotosky and Madeline Davis Tucker	02 EDC 2210	Locaitor	06/01/04	19:01 NCR 153
Ance Bins Rainey, Michele R Rolosky and Madeline Davis Tucker	02 EDC 2310	Lassiter	06/01/04	19:01 NCR 153
ENVIRONMENT AND NATURAL RESOURCES				
Beltex Corporation, a Debtor-in Possession v. DENR, Div of Air Quality	00 EHR 1706	Gray	06/18/04	
			06/04/04	
J.L. Marsh Smith Farms, Inc v. DENR, Div of Air Quality	00 EHR 2116	Gray	00/04/04	
Paymond Wallace The Colden Misser vs. Div of Rediction Protection		Mann	06/17/04	
Raymond Wallace, The Golden Mirror vs. Div of Radiation Protection	01 EHR 1558	Maiii	00/1//04	
Raymond Wanace, The Golden Militor vs. Div of Radiation Flotection	01 EHR 1558	Widili	00/17/04	
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CONTESTED CASE DECISIONS

James A. Ray v. Hoyte Phifer and Facility Services Management, UNC Greensboro	03 OSP 2453	Elkins	06/01/04
Terry H. Mitchell v. Elizabeth City State University	04 OSP 0015	Conner	07/23/04
Miracle L. Smith v. NC State Highway Patrol	04 OSP 0039	Gray	07/14/04
Samuel Williams v. DOC, Div of Alcoholism, Chemical Dependency Programs	04 OSP 0194	Mann	06/09/04
Jerry William Wiley v. Div of Public Health and DHHS	04 OSP 0210	Elkins	06/23/04
Barbara Hoffner v. DOC, Div of Prisons, Central Prison	04 OSP 0415	Chess	06/17/04
Jeff Nichols v. DOC	04 OSP 0419	Conner	06/29/04
Phyllis Holt v. UNC Chapel Hill	04 OSP 0486	Chess	06/01/04
John V. Smith v. NCSU	04 OSP 0505	Chess	06/17/04
Mark A. Boyce v. Dept. of Commerce	04 OSP 0543	Gray	07/06/04
Eldredia B. Mizelle v. Craven Correctional Institution, Dept. of Corrections,	04 OSP 0582	Wade	06/24/04
David W. Chester, Capt. Kathryn Brown			
Bernadine Ralph v. O'Berry Center	04 OSP 0706	Lassiter	06/29/04
James A. Ray v. UNC at Greensboro, Facility Services	04 OSP 0751	Elkins	07/14/04
Gwendolyn Robertson Horton v. DHHS	04 OSP 0792	Morrison	07/26/04
Veronica J. Johnson v. SOS	04 OSP 0961	Morrison	07/23/04
Gregory Tabron v. John Umstead Hospital	04 OSP 1014	Lassiter	07/26/04
UNC HOSPITALS			
Carrie Ann Sykes v. Chapel Hill Hospital	04 UNC 0245	Elkins	06/25/04
Danielle Catoe v. UNC Hospitals	04 UNC 0291	Elkins	06/25/04
Rex A. Coughenour v. UNC Hospitals	04 UNC 0306	Elkins	06/22/04
P. Nettles v. UNC Hospitals	04 UNC 0393	Morrison	07/23/04
Joe Hatcher v. UNC Hospitals	04 UNC 0480	Morrison	07/23/04
Tammy Bottoms v. UNC Hospitals	04 UNC 0502	Elkins	07/21/04
Thomas Sherman Tate v. UNC Hospitals	04 UNC 0538	Chess	06/15/04
Tracy Lane v. UNC Hospitals	04 UNC 0601	Gray	07/23/04
Chris Oduok v. UNC Hospitals	04 UNC 0760	Morrison	07/26/04
Pamela L. Chevalier v. UNC Hospitals	04 UNC 0773	Morrison	07/26/04

STATE OF NORTH CAROLINA COUNTY OF WAKE JOHN N. LEAK, Petitioner, v. DECISION N.C. DEPARTMENT OF PUBLIC INSTRUCTION, Respondent.

This case came on for hearing before the undersigned on March 3, 2004, in the Lee House Hearing Room, 422 North Blount Street, Raleigh, North Carolina.

APPEARANCES

For the Petitioner: David G. Schiller

Schiller & Schiller

Suite 101

5540 Munford Road Raleigh, NC 27612

For the Respondent: Laura E. Crumpler

Assistant Attorney General N. C. Department of Justice

P. O. Box 629 Raleigh, NC 27602

ISSUES

- 1. Whether Petitioner was discharged from employment for just cause.
- 2. Whether Respondent's letter of dismissal met the specificity requirement of G.S. 126-35.

Having heard and considered the testimony and exhibits in light of applicable law, the undersigned makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

- 1. Petitioner was, at all times relevant to the matters involved, employed by Respondent North Carolina Department of Public Instruction as a consultant in the Alternative and Safe Schools Section. Petitioner, at the time of the events in this case, had been employed by Respondent for more than 24 consecutive months.
- 2. In that capacity, Petitioner reported to Marguerite Peebles, Section Chief, Alternative and Safe Schools and Instructional Support Section. (T p. 15) That Section is Responsible for Providing technical assistance and monitoring to local school systems in the areas involving alternative learning programs, safe and drug-free schools, school counselors, school social workers, and school psychologists. The Section also is responsible for overseeing compliance with the No Child Left Behind Act. ("NCLB"). (T pp. 16, 23, 30)
- 3. In 2003, one of the responsibilities of the consultants in the Alternative and Safe School Sections was to go out and visit various schools across the State which were at risk of being labeled "persistently dangerous schools" under the NCLB Act. (T p. 30) The observations and assessments from those site visits were to be compiled into a report for the State Board of Education, which would then determine whether to label the school as "persistently dangerous." (T pp. 31-32)
- 4. Petitioner was assigned to several schools to conduct site visits, including Monroe Middle School in Union County. (T pp. 33-34) The site teams were given instructions as to the expectations for their behavior at the schools and the protocol for their visits. (T pp. 34-35)

- 5. Dr. Ed Davis, Assistant Superintendent of Auxiliary Services for Union County Schools, already had advised the Principal of Monroe Middle School, Ms. Rose Burns, about the purpose of the site visit and to prepare for it. (T p. 40)
- 6. Dr. Davis arrived at the Middle School on May 8, 2003, in order to be present for the team's exit interview with Ms. Burns. (T p. 41)
- 7. Earlier that morning, Ms. Regina Taylor-Dillard arrived at school to begin her duties as Administrative Assistant to Ms. Burns, the Principal. On this day, she was asked to fill in as a substitute for a teacher who had been called out for a family emergency. (T pp. 60-62)
- 8. The teacher had not left a lot of work for the students in the classroom and Ms. Taylor-Dillard felt that she was mostly there just to supervise the students. (T p. 62) As the students sat and talked and waited for a movie to arrive Petitioner came into the classroom to observe. Petitioner took a seat near the rear of the room and observed that the classroom was in disarray. Soon after Petitioner's arrival, Ms. Taylor-Dillard, seated at a computer on one side of the classroom, went to the front of the room and called the class to order. After observing the class, Petitioner walked to the front of the room to speak with Ms. Taylor-Dillard. Ms. Taylor-Dillard testified that

[H]e approached me. . . he came around towards me and pulled the chair up, and he gave me a book to look at what my - what he gave me in the classroom. I felt uncomfortable at that time when he approached me and sat down and he was too close to me, so I looked at the book and I kind of skimmed through it to give it back to him so maybe - hoping that when I give it back to him, maybe he'll - you know, I give it back to him and he'll leave because I felt uncomfortable with how close he was upon me.

(T pp. 68-69) At the hearing, she testified that Petitioner invaded her personal space.

- 9. Petitioner and Ms. Taylor-Dillard talked at the front of the classroom about his visit and observations. It was not a lengthy conversation, perhaps five minutes or less. The participants to that conversation differ widely on the substance of it and the conduct exhibited during the conversation. Ms. Taylor-Dillard testified that Petitioner sat side by side with her and held a book which had the effect of hiding his hand from the students while he rubbed her right leg with his left hand. She gave a courtroom demonstration showing that her chair and Petitioner's chair were sitting side by side facing the classroom. She testified that he asked about her children and stated that he wished that he had met her earlier. She also testified that when Petitioner got ready to leave, that he rubbed her arm with his hand all the way to her elbow.
- 10. Ms. Taylor-Dillard testified that she was extremely upset after Petitioner left her classroom and that she attempted to call the school administration to report the problem but was unable to locate anyone. She did get in touch with the School Resource Officer William Kilgo who happened down the hallway and saw her looking upset and stopped to inquire about her status. Officer Kilgo took Ms. Taylor-Dillard to the principal's office and called the principal out of a meeting whereupon Ms. Taylor-Dillard told Principal Burns about the incident.
- 11. Later that day, Assistant Superintendent Ed Davis interviewed Ms. Taylor-Dillard about the events of the day. Ms. Taylor-Dillard told Superintendent Davis that she was sitting at the teacher's desk when Petitioner approached and sat in a chair facing her. This statement is in contrast to the testimony she gave under oath in the hearing along with her courtroom demonstration that she and Petitioner sat side by side in chairs. She told Superintendent Davis that Petitioner rubbed her left leg with his right hand. This statement is in contrast to the testimony she gave under oath in the hearing that Petitioner rubbed her right leg with his left hand.
- 12. Later that day, as Petitioner and other members of his team were about to leave, Petitioner walked by Ms. Taylor-Dillard and Officer Kilgo who were together in or near the cafeteria carrying out student monitoring duties. Petitioner attempted to shake hands with both of them but Officer Kilgo refused and told Petitioner that he needed to have a private word with him. Officer Kilgo told Petitioner about the allegations made by Ms. Taylor-Dillard of inappropriate remarks and unwelcome touching by Petitioner. Petitioner denied the remarks and touching and went to see Principal Burns to advise her of his position regarding the allegations.
- 13. Assistant Superintendent Davis conducted an investigation of the incident on behalf of the school system and ultimately the Union County Superintendent of Schools, Dr. Jerry Thomas. Dr. Davis contacted Marvin Pittman at the Department of Public Instruction to report the incident. (T p. 174) After this initial contact from Union County Schools, the matter was investigated by the Office of Personnel Relations at the Department of Public Instruction. Michael Thornton, Director of that office, and Pearla Alston, Assistant Director, interviewed, through telephone calls, Dr. Davis, Ms. Burns, Officer Kilgo, and Ms. Taylor-Dillard. Assistant Director Alston testified at the hearing that she believed Ms. Taylor-Dillard because Ms. Taylor-Dillard almost broke down

during the telephone interview and almost cried. Neither Director Thornton nor Assistant Director Alston interviewed Ms. Taylor-Dillard in person.

- 14. Following the telephone interviews with Union County personnel, Mr. Pittman called together a meeting at Department of Public Instruction to make inquiry into Petitioner's version of the events in Union County. (T pp. 133-34) Present at that meeting were Marvin Pittman, Elsie Leak, Michael Thornton, Pearla Alston, and Petitioner. (T pp. 133-34)
- 15. At the beginning of the meeting, Michael Thornton noted that there were serious charges being made against Petitioner and handed Petitioner a typewritten summary of the incident originally prepared by Dr. Davis. This written summary was admitted into evidence as Respondent's Exhibit six (6) and contained the date, place, particular acts complained of, and the name of the complaining witness, Ms. Regina Taylor-Dillard. (Ex. 6; T p. 143)
- 16. According to everyone present at that meeting, except for Petitioner, Petitioner glanced at the paper for ten seconds or less, threw it down and said "This is ludicrous." (T pp. 134, 168, 183, 190) At Director Thornton's urging, Petitioner then picked up the document and read the charges and stated that he did not do it.
 - 17. Petitioner at all times denied that he engaged in the alleged misconduct.
- 18. Petitioner at no time ever reported to his supervisor that allegations of misconduct had been raised by Ms. Taylor-Dillard in Union County. (T p. 135) Dr. Elsie Leak, Associate Superintendent for Curriculum and School Reform Services at the Department of Public Instruction, and Marvin Pittman, Director of the Division of School Improvement at the Department of Public Instruction, both were disturbed that they first heard of the allegations from Union County Assistant Superintendent Davis rather than Petitioner.
- 19. Following the initial meeting in which Department of Public Instruction Officials confronted Petitioner, additional discussions were held to explore appropriate disciplinary action. (T p. 135)
- 20. On September 4, 2003, Dr. Elsie Leak wrote to Petitioner and notified him that the Department was considering dismissal "based on the results of an investigation of charges you sexually harassed an employee of the Union County School System during a site visit for the Department of Public Instruction." (Resp. Ex. 13)
- 21. At the predismissal hearing conducted on September 4, 2003, Department of Public Instruction officials "implored" Petitioner "to tell us, you know, is there something that we need to know, something that will help us with this." There was "very little forthcoming in terms of exchange." (T p. 137) Petitioner continued to deny that he had engaged in the conduct alleged by Ms. Taylor-Dillard.
- 22. On September 5, 2003, Dr. Leak wrote to Petitioner notifying him of his "dismissal from Employment" based on unacceptable personal conduct stemming from "the incident between you and a local school system employee as reported to the department on August 18, 2003 ." (Resp. Ex. 14)
- 23. On September 10, 2003, Petitioner filed a grievance alleging lack of just cause in violation of G.S. 126-35, and a failure of the dismissal letter to meet the specificity requirements of G.S. 126-35.
- 24. On September 12, 2003, Dr. Leak responded to Petitioner's grievance by allowing his grievance and reinitiating the action to dismiss Petitioner from employment. (Resp. Ex. 16) The letter reiterates that the grounds for dismissal were fully outlined to Petitioner in the initial conference conducted on August 28, 2003. The letter also reset the effective date for Petitioner's dismissal to September 12, 2003, rather than September 5, 2003, in order to prevent a loss to Petitioner of salary and benefits accruing from the date of the original dismissal till the new effective date. (Resp. Ex. 16)
- 25. Also on September 12, 2003, Dr. Leak sent a new letter of dismissal to Petitioner in which she reiterated that he was being dismissed for "unacceptable personal conduct." (Resp. Ex. 17) The letter went on to recount the events of May 8, 2003, and the subsequent investigations leading up to the dismissal. The letter stated, in pertinent part, as follows:

On August 18, 2003, the Director of the School Improvement Division, Mr. Marvin Pittman, notified the Director of Human Resources that you had been accused of making an inappropriate advance of a sexual nature on an employee at Monroe Middle School in Union County. Mr. Pittman had been informed of this action by the Assistant Superintendent of Union County Schools, Dr. Ed Davis. A copy of the incident as noted by Dr. Davis was sent to Mr. Pittman. After reading Dr. Davis' account of the May 8, 2003 incident, Mr. Michael Thornton, Human Resources Director, and Mrs. Pearla Alston, Assistant Human Resources Director, began an investigation that

included an interview with the alleged victim, an interview with the School Resource Officer, and two or more conversations with the Principal at Monroe Middle School. These interviews were consistent with the employee's version that you had made an unwanted sexual advance toward her. Based upon this information we concluded that you should be dismissed based upon your unacceptable personal conduct. A pre-disciplinary conference was held on September 4, 2003. (Resp. Ex. 17)

- 26. The letter made it clear that the dismissal was effective on September 12, 2003.
- 27. For some unexplained reason, the green card was not returned to the Department even though the September 12, 2003, dismissal letter was sent certified mail, return, receipt requested. Consequently, the Department re-sent the dismissal letters this time dating them September 17, 2003, and this time mailing the letters to two separate addresses in order to ensure that Petitioner received the letters. (Resp. Ex. 18, 19, 20, 21) In these letters, Petitioner's dismissal date was again moved forward in order to negate any loss of salary and benefits that should accrue to him. (Resp. Ex. 18, 19, 20, 21)
- 28. The dismissal letter(s) of September 17, 2003 contained notice of Petitioner's appeal rights in accordance with G.S. 126-35.
- 29. On September 25, 2003, Michael Thornton wrote to Petitioner and informed him that an internal grievance hearing would be held on October 21, 2003. (Resp. Ex. 22)
- 30. On October 9, 2003, Petitioner filed a new grievance contesting the dismissal letters dated September 12 and September 17, 2003.
- 31. On October 28, 2003, Dr. Michael E. Ward, Superintendent, Department of Public Instruction wrote a letter to Petitioner upholding the decision to terminate his employment and informing him of his right to contest the agency action.
 - 32. This contested case was commenced by the filing of a petition on November 10, 2003.
- 33. Annie Davis, Calvin Burnette Kearney, Carla G. Lowery, Carmela Audrey Robinson, Jeannette Johnson McNeal, and Felicia Boone all testified that Petitioner had a reputation for honesty and none ever had seen him behave inappropriately with a female.
 - 34. Respondent offered no contradictory evidence regarding Petitioner's reputation for honesty.
 - 35. Respondent offered no evidence regarding Ms. Taylor-Dillard's reputation for honesty.
- 36. Ms. Taylor-Dillard has undermined her credibility with her inconsistent and contradictory statements made in her interview on May 8, 2003, the incident date, with Assistant Superintendent Davis as compared to her sworn testimony at the hearing. Having observed Ms. Taylor-Dillard's demeanor during the hearing and considering her contradictory statements, I find that her testimony is not credible.
- 37. G.S. 126-35 requires that a career employee be given written notice of the specific acts and omissions constituting just cause for dismissal before the action is taken.
 - 38. "Just cause" as defined in the Administrative Code includes the following:
 - (1) conduct for which no reasonable person should expect to receive a prior warning;
 - (2) job-related conduct which constitutes a violation of state or federal law;
 - (3) the willful violation of known or written work rules;
 - (4) conduct unbecoming a state employee that is detrimental to state service 25 N.C.A.C. 1J.0614.

CONCLUSIONS OF LAW

1. The parties properly are before the Office of Administrative Hearings.

CONTESTED CASE DECISIONS

- 2. Petitioner was a career State employee at the time of his dismissal, a status which requires Respondent to demonstrate just cause under G.S. 126-35 in order to sustain his dismissal.
- 3. In view of the lack of credibility of the complaining witness, Ms. Taylor-Dillard, it is concluded as a matter of law that Respondent has failed to carry the burden of proof demonstrating just cause for its dismissal of Petitioner for reasons of improper personal conduct.
- 4. The specificity requirement set forth in G.S. 126-35 is met when the letter of dismissal describes the employer's conduct "with sufficient particularity so that the discharged employee will know precisely what acts or omissions were the basis of his discharge." *Security Commission v. Wells*, 50 N.C. App. 393, 274 S.E.2d 256 (1981). The employee is entitled to know the acts with which he is charged in order to "respond to agency charges and be able to prepare an effective representation." *Id.*
- 5. Here, the evidence showed that Petitioner was confronted with oral and written charges of his alleged conduct, in a meeting on August 28, 2003, with Michael Thornton, Pearla Alston, Dr. Elsie Leak, and Marvin Pittman. Petitioner was apprised of the factual basis for the allegations both orally and in writing at that meeting, including the name of the complaining party, and was sufficiently aware of those charges to deny them and to prepare his defense.

DECISION

Respondent's dismissal of Petitioner for personal conduct is not supported by the evidence and is REVERSED. It is ordered that Petitioner be reinstated to the Consultant Position he held at the time of his dismissal, or to a substantially similar position, with full backpay accruing from his termination date until paid, further appropriate adjustment of his salary in view of any across the board legislative salary increase, all other benefits of continuous State employment, and attorneys' fees and costs upon proper affidavits, including deposition and transcript costs. It is ordered that Petitioner's personnel file be appropriately rectified so as to reflect that he was terminated without just cause. Any and all documents in his personnel file which indicate to any degree a contrary fact shall be removed. Petitioner shall be retrained if he is placed in a substantially similar position rather than reinstated to his former position.

ORDER

It is hereby ordered that the agency serve a copy of the Final Decision on the Office of Administrative Hearings, 6714 Mail Service Center, Raleigh, North Carolina 27699-6714, in accordance with N.C.G.S. § 150B-36(b).

NOTICE

Before the State Personnel Commission makes the Final Decision, it is required by N.C.G.S. § 150B-36(a) to give each party an opportunity to file exceptions to the administrative law judge's decision, and to present written arguments to those in the agency who will make the Final Decision.

The State Personnel Commission is required by N.C.G.S. § 150B-36(b) to serve a copy of the Final Decision on all parties and to furnish a copy on the parties' attorney of record.

This the 16 th of June, 2004.	
	December D. Const.
	Beecher R. Gray Administrative Law Judge