

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0101

DEADLINE FOR RECEIPT: Friday, December 8, 2017

NOTE WELL: *This request when viewed on computer extends several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On the Submission for Permanent Rule Form, Box 8, you do not indicate state funds are affected; however, the Notice of Text said they were. Please review and revise if necessary.

In Part (d)(1)(A), Page 5, line 22, please remove the underline from (1) and strike it.

Also on line 22, it appears you are missing a closing parenthesis.

In Parts (d)(2)(A) and (B), lines 27 and 28, please underline "(A)" and "(B)". In addition, on line 27, insert a semicolon before "and". Since these changes were published in the Register, you do not need to show these as changes. Simply make the changes.

In Part (d)(2)(B), line 28, is the term "region protease/reverse transcriptase"? Is this a term of art?

On line 29, why are you stating "if available"? Isn't that already addressed on line 26?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

1 10A NCAC 41A .0101 is amended as published in 32:04 NCR 153-155 as follows:

2
3 **10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS**

4 (a) The following named diseases and conditions are declared to be dangerous to the public health and are
5 hereby made reportable within the time period specified after the disease or condition is reasonably suspected to
6 exist:

- 7 (1) acquired immune deficiency syndrome (AIDS) - 24 hours;
- 8 (2) anthrax - immediately;
- 9 (3) botulism - immediately;
- 10 (4) brucellosis - 7 days;
- 11 (5) campylobacter infection - 24 hours;
- 12 (6) chancroid - 24 hours;
- 13 (7) chikungunya virus infection - 24 hours;
- 14 (8) chlamydial infection (laboratory confirmed) - 7 days;
- 15 (9) cholera - 24 hours;
- 16 (10) Creutzfeldt-Jakob disease – 7 days;
- 17 (11) cryptosporidiosis – 24 hours;
- 18 (12) cyclosporiasis – 24 hours;
- 19 (13) dengue - 7 days;
- 20 (14) diphtheria - 24 hours;
- 21 (15) Escherichia coli, shiga toxin-producing - 24 hours;
- 22 (16) ehrlichiosis – 7 days;
- 23 (17) encephalitis, arboviral - 7 days;
- 24 (18) foodborne disease, including Clostridium perfringens, staphylococcal, Bacillus cereus, and other
25 and unknown causes - 24 hours;
- 26 (19) gonorrhea - 24 hours;
- 27 (20) granuloma inguinale - 24 hours;
- 28 (21) Haemophilus influenzae, invasive disease - 24 hours;
- 29 (22) Hantavirus infection – 7 days;
- 30 (23) Hemolytic-uremic syndrome – 24 hours;
- 31 (24) Hemorrhagic fever virus infection – immediately;
- 32 (25) hepatitis A - 24 hours;
- 33 (26) hepatitis B - 24 hours;
- 34 (27) hepatitis B carriage - 7 days;
- 35 (28) hepatitis C, acute – 7 days;

- 1 (29) human immunodeficiency virus (HIV) infection confirmed - 24 hours;
- 2 (30) influenza virus infection causing death – 24 hours;
- 3 (31) legionellosis - 7 days;
- 4 (32) leprosy – 7 days;
- 5 (33) leptospirosis - 7 days;
- 6 (34) listeriosis – 24 hours;
- 7 (35) Lyme disease - 7 days;
- 8 (36) Lymphogranuloma venereum - 7 days;
- 9 (37) malaria - 7 days;
- 10 (38) measles (rubeola) - 24 hours;
- 11 (39) meningitis, pneumococcal - 7 days;
- 12 (40) meningococcal disease - 24 hours;
- 13 (41) Middle East respiratory syndrome (MERS) - 24 hours;
- 14 (42) monkeypox – 24 hours;
- 15 (43) mumps - 7 days;
- 16 (44) nongonococcal urethritis - 7 days;
- 17 (45) novel influenza virus infection – immediately;
- 18 (46) plague - immediately;
- 19 (47) paralytic poliomyelitis - 24 hours;
- 20 (48) pelvic inflammatory disease – 7 days;
- 21 (49) psittacosis - 7 days;
- 22 (50) Q fever - 7 days;
- 23 (51) rabies, human - 24 hours;
- 24 (52) Rocky Mountain spotted fever - 7 days;
- 25 (53) rubella - 24 hours;
- 26 (54) rubella congenital syndrome - 7 days;
- 27 (55) salmonellosis - 24 hours;
- 28 (56) severe acute respiratory syndrome (SARS) – 24 hours;
- 29 (57) shigellosis - 24 hours;
- 30 (58) smallpox - immediately;
- 31 (59) Staphylococcus aureus with reduced susceptibility to vancomycin – 24 hours;
- 32 (60) streptococcal infection, Group A, invasive disease - 7 days;
- 33 (61) syphilis - 24 hours;
- 34 (62) tetanus - 7 days;

- (63) toxic shock syndrome - 7 days;
- (64) trichinosis - 7 days;
- (65) tuberculosis - 24 hours;
- (66) tularemia – immediately;
- (66) typhoid - 24 hours;
- (67) typhoid carriage (*Salmonella typhi*) - 7 days;
- (68) typhus, epidemic (louse-borne) - 7 days;
- (69) vaccinia – 24 hours;
- (70) vibrio infection (other than cholera) – 24 hours;
- (71) whooping cough – 24 hours; and
- (72) yellow fever - 7 days.
- (b) For purposes of reporting, "confirmed human immunodeficiency virus (HIV) infection" is defined as a positive virus culture, repeatedly reactive EIA antibody test confirmed by western blot or indirect immunofluorescent antibody test, positive 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 cayentanesis*, 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) Middle East respiratory syndrome virus.
- (X) Monkeypox.
- (Y) *Mycobacterium leprae*, the cause of leprosy.
- (Z) *Plasmodium falciparum*, *P. malariae*, *P. ovale*, and *P. vivax*, the causes of malaria in humans.
- (AA) Poliovirus (any), the cause of poliomyelitis.
- (BB) Rabies virus.
- (CC) *Rickettsia rickettsii*, the cause of Rocky Mountain spotted fever.
- (DD) Rubella virus.
- (EE) *Salmonella* spp., the causes of salmonellosis.
- (FF) *Shigella* spp., the causes of shigellosis.
- (GG) Smallpox virus, the cause of smallpox.
- (HH) *Staphylococcus aureus* with reduced susceptibility to vanomycin.
- (II) *Trichinella spiralis*, the cause of trichinosis.
- (JJ) Vaccinia virus.
- (KK) *Vibrio* spp., the causes of cholera and other vibrioses.
- (LL) Yellow fever virus.
- (MM) *Yersinia pestis*, the cause of plague.
- (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.
- (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 and all results from tests to determine HIV viral load.
- (d) Laboratories utilizing electronic laboratory reporting (ELR) shall ~~report-report~~:
- (1) ~~All-all~~ positive laboratory results from tests used to diagnosis ~~chronic hepatitis C infection, including- Hepatitis C Infection, including the following:~~
 - (1)(A) Hepatitis C virus antibody tests (including the test specific signal to cut-off (s/c) ratio;
 - (2)(B) Hepatitis C nucleic acid tests;
 - (3)(C) Hepatitis C antigen(s) tests; and
 - (4)(D) Hepatitis C genotypic tests.
- (2) All HIV genotypic test results, including when available:
- (A) The entire nucleotide sequence and
 - (B) The pol region sequence (including all regions protease (PR)/reverse transcriptase (RT) and integrase inhibitor (INI) genes), if available.
- History Note: Authority G.S. 130A-134; 130A-135; 130A-139; 130A-141:*
Amended Eff. October 1, 1994; February 1, 1990;
Temporary Amendment Eff. July 1, 1997;
Amended Eff. August 1, 1998;
Temporary Amendment Eff. February 13, 2003; October 1, 2002; February 18, 2002; June 1, 2001;
Amended Eff. April 1, 2003;
Temporary Amendment Eff. November 1, 2003; May 16, 2003;

1 *Amended Eff. January 1, 2005; April 1, 2004;*
2 *Temporary Amendment Eff. June 1, 2006;*
3 *Amended Eff. April 1, 2008; November 1, 2007; October 1, 2006;*
4 *Temporary Amendment Eff. January 1, 2010;*
5 *Temporary Amendment Expired September 11, 2011;*
6 *Amended Eff. July 1, 2013;*
7 *Temporary Amendment Eff. December 2, 2014;*
8 *Amended Eff. October 1, 2015;*
9 *Emergency Amendment Eff. March 1, 2016;*
10 *Temporary Amendment Eff. July 1, 2016;*
11 *Amended Eff. January 1, 2018; October 1, 2016.*
12

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 41A .0202

DEADLINE FOR RECEIPT: Friday, December 8, 2017

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

In Sub-Item (1)(a)(i), line 9, is "adherent with" the correct terminology? I just wanted to confirm that.

Line 10, please simply remove the errant "n" before "of"

Lines 12 and 13, delete the "or" at the end of the line.

In Sub-Item (1)(a)(iii), line 14, since I am not familiar with this terminology, I am simply asking - should the parenthesis end after "PrEP"? Should it read "HIV Pre-Exposure Prophylaxis (PrEP), which is an antiretroviral medication..."

In Sub-Item (1)(a)(iv), line 17, couldn't you simply delete "condoms were not used by the person living with HIV at the time of the sexual because" since it repeats line 8?

If you need to retain it, please note that you published "intercourse" after "sexual" on line 17 and should keep the language.

In Sub-Item (1)(c)(i), lines 26-27, please replace "subsection (a) and (b) of Section 274f-5 of Title 42 of the United States Code" with "42 USC 274f-5(a) and (b)"

On lines 28 and 31, if the intent is to refer to 42 USC 247f-5(c), please state that. And do you need the cross-reference on both lines?

In Sub-Item (1)(c)(ii), does this count as "donation or selling" as set forth on line 22?

In Sub-Item (1)(d), line 35, delete the "and"

In Sub-Item (1)(e), Page 2, line 2, so that I'm clear – you meant to cite to (1)(a)(i) and not (1)(a)(iv)? I ask because it seems that (1)(a)(iv) is what you meant. Should you cite to (1)(a)(iv) in the next sentence on lines 2-3?

Also on line 2, please capitalize "Rule"

Amanda J. Reeder
Commission Counsel

Date submitted to agency: November 28, 2017

On line 3, please properly delete the comma and “and” that you published and replace them with a semicolon.

In Sub-Item (1)(f), line 7, delete the comma after “and”

In Sub-Item (2)(a), line 14, what are these “control measures”? I know the term is used in G.S. 130A-144, but what are they in this Rule? Are they what are in Sub-Item (1)(d)?

In Sub-Item (2)(c), line 21, is the fax number known to the regulated public?

Also on line 21, end the sentence after “fax.” Then state “The Division...”

On line 22, what do you mean by “undertake”?

On line 22, delete the semicolon after “spouse” and replace it with “and”

On line 23, replace “is” with “shall be”

In Sub-Item (2)(d), line 25, what are “proper” methods? Is this defined somewhere or a term of art?

In Item (3), lines 29-30, and elsewhere in the Rule that the term is used, what is a “significant risk of transmission”? Is this term defined? Is it defined on lines 30-31 (open wounds, behavioral abnormalities)?

On line 31, what are “behavioral abnormalities”? Is this defined somewhere?

In Sub-Item (3)(a), lines 35-36, what is a “medical expert”? Who determines this?

On line 37, what is being investigated? Is it the determination of a risk or if the risk is “significant”?

On Page 3, line 1, and elsewhere the term is used, is this the county superintendent?

On lines 1, 8, and 11, replace “such a” with “this”

On line 2, is this for the risk of any transmission or “significant” risk

On lines 5-8, this standard is not available online? Is this the url?

<https://www.cdc.gov/hiv/risk/estimates/index.html> If so, why not include that rather than stating that the document can be received through CPH, as G.S. 150B-21.6 requires the agency to maintain a copy for inspection?

In Sub-Item (3)(b)(vi), line 29, what are these instructions going to address? HIPAA?

In Sub-Item (3)(c), lines 32-33, what are these “alternate child care settings” referred to here?

In Item (4), how is a “significant risk of HIV transmission” determined? By whom?

In Sub-Item (4)(a)(i), Page 4, lines 6-8, what is your authority for this? G.S. 130A-148(h) allows testing without informed consent under specific circumstances, but the rule does not seem to address this.

Further, G.S. 130A-148(h) allows testing of adults for AIDS, not HIV. Aren't these different? What is the authority for this?

On line 9, consider replacing "an existing specimen, if one exists" with "any existing specimen"

Just out of curiosity – what if there is no existing specimen? Does (4)(a)(ii) apply?

In Sub-Item (4)(a)(ii), line 15, and (4)(b), line 24, define "reasonable intervals" Is this governed by the CDC HIV testing guidelines?

On line 17, have you incorporated by reference these testing guidelines elsewhere, or do you need to do so here?

On line 19, is the cross-reference to Sub-Items (1)(a) through (c) still correct? And are these the same control measures addressed in Sub-Item (2)(a)?

On lines 19-21, what does this mean? Is this to reference HIPAA?

In Item (5), lines 28 and 31, what do you mean by "good faith"?

On lines 29 and 31, define "reasonable cause"

In Item (6), line 34, delete the comma after "Rule"

On line 36, please confirm if "mental health authority" is still the correct term.

In Item (10), Page 5, line 17, I am just checking - is the term "control measures counseling"?

In Item (11), line 25, what is "linkage to care"? Is it what is stated in Item (10), lines 16-17? Does your regulated public know what this means?

On line 26, what is "appropriate"? Will this be determined for each individual?

In Sub-Item (11)(b), what are "harm reduction services"?

In Sub-Item (11)(c), line 29, what do you mean by "required"?

Sub-Item (11)(d), line 31, the addition of "and" at the end of the line is new and should be underlined.

In Sub-Item (11)(e), what is this? Does your regulated public know?

In Item (12), isn't this addressed by addressed by Sub-Item (2)(c)?

What is your authority for Item (13), Page 6, lines 1-6?

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

On line 4, what is a “rapid HIV test”

On line 4, define “reasonably” and reasonable to whom? The physician?

In Item (15), line 19, replace “which” with “that”

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

NCAC 41A .0202 is amended with changes as published in 32:05 NCR 279-283 as follows:

10A NCAC 41A .0202 CONTROL MEASURES – HIV

The following are the control measures for the ~~Acquired Immune Deficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) infection:~~

(1) ~~Infected persons shall:~~ Persons diagnosed with HIV infection (hereafter “person living with HIV”) shall:

(a) refrain from sexual intercourse unless condoms are used except when:

(i) the person living with HIV is in HIV care, is ~~compliant~~ adherent with the treatment plan of the attending physician, and had been virally suppressed for at least 6 months (HIV levels below 200 copies per milliliter) at the time of sexual intercourse; or

(ii) the sexual intercourse partner is HIV positive; or

(iii) the sexual intercourse partner is taking HIV Pre-Exposure Prophylaxis (PrEP – antiretroviral medication used to prevent HIV infection) as directed by an attending physician; or

(iv) condoms were not used by the person living with HIV at the time of the sexual intercourse because sexual intercourse occurred in the context of a sexual ~~assault, assault~~ in which the person living with HIV was the victim.

(b) not share needles or syringes, or any other drug-related equipment, paraphernalia, or works that may be contaminated with blood through previous use;

(c) not donate or sell blood, plasma, platelets, other blood products, semen, ova, tissues, organs, or breast ~~milk;~~ milk except when:

(i) The person living with HIV is donating organs as part of a clinical research study that has been approved by an institutional review board under the criteria, standards, and regulations described in subsection (a) and (b) of Section 274f-5 of Title 42 of the United States Code, or, if the United States Secretary of Health and Human Services determines under subsection (c) of Title 42 of the United States Code that participation in this clinical research is no longer warranted as a requirement for transplants, and the organ recipient is receiving the transplant under the criteria, standards, and regulations of Subsection (c) of Title 42 of the United States Code; or

(ii) Sperm or ova are harvested under the supervision of an attending physician to be used by the person’s spouse or partner for the purpose of achieving pregnancy.

(d) have a ~~skin~~ test for tuberculosis; and,

- (e) notify future sexual intercourse partners of the ~~infection~~; infection, unless the person living with HIV meets the criteria listed in (1)(a)(i) of this rule. If the person living with HIV is the victim of a sexual assault, there is no requirement to notify the assailant.; and
- (f) if the time of initial infection is known, notify persons who have been sexual intercourse ~~and or needle-~~ needle-sharing partners since the date of infection or give the names to a disease intervention specialist employed by the local health department or by the Division of Public Health for contact tracing and notification; and,
- (g) if the date of initial infection is unknown, notify persons who have been sexual intercourse ~~d-needle or needle-sharing~~ partners for the previous year-12 months or give names to a disease intervention specialist employed by the local health department or by the Division of Public Health for contact tracing of all sexual and needle-sharing partners for the preceding 12 months.
- (2) The attending physician shall:
- (a) give the control measures in Item (1) of this Rule to patients living with HIV in accordance with 10A NCAC 41A .0210;
- ~~(b)~~ advise persons living with HIV to notify all future sexual partners of infection;
- ~~(c)(b)~~ If the attending physician knows the identity of the spouse of ~~an HIV-infected patient~~ the person living with HIV and has not, with the consent of the ~~infected patient~~ person living with HIV, notified and counseled the spouse, the physician shall list the spouse on a form provided by the Division of Public Health and shall ~~mail send~~ send the form to the ~~Division;~~ Division by secure transmission, required by 45 CFR 164.312(e)(1), or fax; the Division shall undertake to counsel the spouse; the attending physician's responsibility to notify exposed and potentially exposed persons is satisfied by fulfilling the requirements of Sub-Items (2)(a) and (c) (b) of this Rule;
- ~~(d)(e)~~ advise infected persons living with HIV concerning proper methods for the clean-up of blood and other body fluids;
- ~~(e)(d)~~ advise infected persons living with HIV concerning the risk of perinatal transmission and transmission by breastfeeding.
- (3) The attending physician of a child ~~who is infected~~ living with HIV ~~and~~ who may pose a significant risk of transmission in the school or day care setting because of open, oozing wounds or because of behavioral abnormalities ~~such as biting~~ shall notify the local health director. The local health director shall consult with the attending physician and investigate the following circumstances:
- (a) If the child is in school or scheduled for admission and the local health director determines that there may be a significant risk of transmission, the local health director shall consult with an interdisciplinary committee, which shall include school personnel, a medical expert, and the child's ~~parent parents~~ or ~~legal guardian guardians~~ to assist in the investigation and determination of risk. The local health director shall notify the

1 superintendent or private school director of the need to appoint such an interdisciplinary
2 committee. Risk of transmission shall be determined in accordance with the HIV Risk and
3 Prevention Estimates published by the Centers for Disease Control and Prevention, which
4 are hereby incorporated by reference including subsequent amendments and editions. A
5 copy of this publication is on file for public viewing and may be obtained free of charge
6 by writing the Division of Public Health, 1915 Mail Service Center, Raleigh, North
7 Carolina 27699-1915.

8 (i) If the superintendent or private school director establishes such a committee
9 within three days of notification, the local health director shall consult with this
10 committee.

11 (ii) If the superintendent or private school director does not establish such a
12 committee within three days of notification, the local health director shall
13 establish such a committee.

14 (b) If the child is in school or scheduled for admission and the local health director determines,
15 after consultation with the committee, that a significant risk of transmission exists, the local
16 health director shall:

17 (i) notify the ~~parents;~~ parents or legal guardians;

18 (ii) notify the committee;

19 (iii) assist the committee in determining whether an adjustment can be made to the
20 student's school program to eliminate significant risks of transmission;

21 (iv) determine if an alternative educational setting is necessary to protect the public
22 health;

23 (v) instruct the superintendent or private school director concerning protective
24 measures to be implemented in the alternative educational setting developed by
25 school personnel; and

26 (vi) consult with the superintendent or private school director to determine which
27 school personnel directly involved with the child need to be notified of the HIV
28 infection in order to prevent transmission and ensure that these persons are
29 instructed regarding the necessity for protecting confidentiality.

30 (c) If the child is in day care and the local health director determines that there is a significant
31 risk of transmission, the local health director shall notify the parents or legal guardians that
32 the child must be placed in an alternate child care setting that eliminates the significant risk
33 of transmission.

34 (4) When health care workers or other persons have a needlestick or nonsexual non-intact skin or
35 mucous membrane exposure to blood or body fluids that, if the source were ~~infected with HIV,~~ HIV
36 positive, would pose a significant risk of HIV transmission, the following shall apply:

37 (a) When the source person is known:

- (i) The attending physician or occupational health care provider responsible for the exposed person, if other than the attending physician of the person whose blood or body fluids is the source of the exposure, shall notify the attending physician of the source that an exposure has occurred. The attending physician of the source person shall discuss the exposure with the source and, unless the source is already known to be ~~infected~~, living with HIV, shall test the source for HIV infection with or without consent unless it reasonably appears that the test cannot be performed without endangering the safety of the source person or the person administering the test. If the source person cannot be tested, an existing specimen, if one exists, shall be tested. The attending physician of the ~~exposed person source person~~ shall ~~be notified~~ notify the attending physician of the exposed person of the infection status of the source.
- (ii) The attending physician of the exposed person shall inform the exposed person about the infection status of the source, offer testing for HIV infection as soon as possible after exposure and at reasonable intervals ~~up to one year to determine whether~~ until the interval since last exposure is sufficient to assure detection using current CDC HIV testing guidelines. ~~transmission occurred~~, and, if the source person was HIV ~~positive, infected~~, give the exposed person the control measures listed in Sub-Items (1)(a) through (c) of this Rule. The attending physician of the exposed person shall instruct the exposed person regarding the necessity for protecting confidentiality of the source person's HIV status.
- (b) When the source person is unknown, the attending physician of the exposed persons shall inform the exposed person of the risk of transmission and offer testing for HIV infection as soon as possible after exposure and at reasonable intervals until the interval since the last exposure is sufficient to assure detection using the current CDC HIV testing guidelines.
- (c) A health care facility may release the name of the attending physician of a source person upon request of the attending physician of an exposed person.
- (5) The attending physician shall notify the local health director when the physician, in good faith, has reasonable cause to suspect a patient ~~infected~~ living with HIV is not following or cannot follow control measures and is thereby causing a significant risk of transmission. Any other person may notify the local health director when the person, in good faith, has reasonable cause to suspect a person ~~infected~~ living with HIV is not following control measures and is thereby causing a significant risk of transmission.
- (6) When the local health director is notified pursuant to Item (5) of this Rule, of a person who is mentally ill or ~~mentally retarded~~, intellectually impaired, the local health director shall confer with the attending mental health physician or mental health authority and the physician, if any, who notified the local health director to develop a plan to prevent transmission.

- (7) The Division of Public Health shall notify the Director of Health Services of the North Carolina Department of ~~Correction~~ of Public Safety and the prison facility administrator when any person confined in a state prison is determined to be ~~infected~~ living with HIV. If the prison facility administrator, in consultation with the Director of Health Services, determines that a confined ~~HIV infected~~ person living with HIV is not following or cannot follow prescribed control measures, thereby presenting a significant risk of HIV transmission, the administrator and the Director shall develop and implement jointly a plan to prevent transmission, including making recommendations to the unit housing classification committee.
- (8) The local health director shall ensure that the health plan for local jails include education of jail staff and prisoners about HIV, how it is transmitted, and how to avoid acquiring or transmitting this infection.
- (9) Local health departments shall provide counseling and testing for HIV infection at no charge to the patient. Third party payors may be billed for HIV counseling and testing when such services are provided and the patient provides written consent.
- (10) HIV pre-test counseling is not required. Post-test counseling for persons ~~infected~~ living with HIV is required, must be individualized, and shall include referrals for medical and psychosocial services and control ~~measures~~. measures counseling-counseling.
- ~~(11) A local health department or the Department may release information regarding an infected person pursuant to G.S. 130A-143(3) only when the local health department or the Department has provided direct medical care to the infected person and refers the person to or consults with the health care provider to whom the information is released.~~
- ~~(11)~~(12) Notwithstanding Rule .0201(d) of this Section, a local or state health director may require, as a part of an isolation order issued in accordance with G.S. 130A-145, compliance with a plan to assist the individual to comply with control measures. The plan shall be designed to meet the specific needs of the individual including linkage to care and may include referral to one or more of the following available and appropriate services:
- (a) substance abuse counseling and treatment;
 - (b) harm reduction services;
 - ~~(b)~~ (c) mental health counseling and ~~treatment;~~ treatment required to prevent transmission; and,
 - ~~(d)~~ (e) education and counseling sessions about HIV, HIV transmission, and behavior change required to prevent transmission; and
 - (e) intimate partner violence intervention services.
- ~~(12)~~(13) The Division of Public Health shall conduct a partner notification program to assist in the notification and counseling of partners of ~~HIV infected persons.~~ persons living with HIV.
- ~~(13)~~(14) Every pregnant woman shall be offered HIV testing by her attending physician at her first prenatal visit and in the third trimester. The attending physician shall test the pregnant woman for HIV infection, unless the pregnant woman refuses to provide informed consent pursuant to G.S. 130A-

148(h). If there is no record at labor and delivery of an HIV test result during the current pregnancy for the pregnant woman, the attending physician shall inform the pregnant woman that an HIV test will be performed, explain the reasons for testing, and the woman shall be tested for HIV without consent using a rapid HIV test unless it reasonably appears that the test cannot be performed without endangering the safety of the pregnant woman or the person administering the test. If the pregnant woman cannot be tested, an existing specimen, if one exists that was collected within the last 24 hours, shall be tested using a rapid HIV test. The attending physician must provide the woman with the test results as soon as possible. ~~However, labor and delivery providers who do not currently have the capacity to perform rapid HIV testing are not required to use a rapid HIV test until January 1, 2009.~~

~~(14)(15)~~ If an infant is delivered by a woman with no record of the result of an HIV test conducted during the pregnancy and if the woman was not tested for HIV during labor and delivery, the fact that the mother has not been tested creates a reasonable suspicion pursuant to G.S. 130A-148(h) that the newborn has HIV infection and the infant shall be tested for HIV. An infant born in the previous 12 hours shall be tested using a rapid HIV test. ~~However, providers who do not currently have the capacity to perform rapid HIV testing shall not be required to use a rapid HIV test until January 1, 2009.~~

~~(15)(16)~~ Testing for HIV may be offered as part of routine laboratory testing panels using a general consent which is obtained from the patient for treatment and routine laboratory testing, so long as the patient is notified that they are being tested for HIV and given the opportunity to refuse.

*History Note: Authority G.S. 130A-135; 130A-144; 130A-145; 130A-148(h);
Temporary Rule Eff. February 1, 1988, for a period of 180 days to expire on July 29, 1988;
Eff. March 1, 1988;
Amended Eff. February 1, 1990; November 1, 1989; June 1, 1989;
Temporary Amendment Eff. January 7, 1991 for a period of 180 days to expire on July 6, 1991;
Amended Eff. May 1, 1991;
Recodified from 15A NCAC 19A .0201 (d) and (e) Eff. June 11, 1991;
Amended Eff. August 1, 1995; October 1, 1994; January 4, 1994; October 1, 1992;
Temporary Amendment Eff. February 18, 2002; June 1, 2001;
Amended Eff. **January 1, 2018**; November 1, 2007; April 1, 2005; April 1, 2003.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 43D .0710

DEADLINE FOR RECEIPT: Friday, December 8, 2017

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

You did not publish this Rule because you are making amendments pursuant to G.S. 150B-21.5(a)(3). Therefore, the following changes need to be made to reflect this:

On the Submission for Permanent Rule filing form, Box 6, please include the citation to this law beside "Notice not required under G.S."

Also, please provide the date of adoption by the agency in that box.

In the Introductory Statement to the Rule, replace what you have with: 10A NCAC 43D .0710 is amended without notice pursuant to G.S. 150B-21.5(a)(3) as follows:

In the Rule:

In (a), line 5, "State" should be capitalized to be consistent with Rule .0202(18).

In (a)(1), line 8, please replace "which" with "that"

In (e), Page 4, line 24, and (f)(3), Page 5, line 3, what do you mean by "conclusively"?

In the History Note, Page 6, state:

*History Note: Authority G.S. 130A-361; 7 C.F.R. 246; 42 U.S.C. 1786;
Eff. February 1, 2013;
Amended Eff. January 1, 2018.*

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

1 10A NCAC 43D .0710 is adopted with changes as follows

2
3 **10A NCAC 43D .0710 VENDOR VIOLATIONS AND SANCTIONS**

4 (a) Title 7 C.F.R. 246.12(l)(1)(i) through (vi) and (xii) are incorporated by reference with all subsequent amendments
5 and editions. In accordance with 7 C.F.R. 246.12(l)(1)(i), the state agency shall not allow imposition of a civil money
6 penalty in lieu of disqualification for a vendor permanently disqualified. A pattern, as referenced in 7 CFR 246.12
7 (l)(1)(iii)(B) through (F) and 246.12(l)(1)(iv)(A), shall be established as follows:

- 8 (1) claiming reimbursement for the sale of an amount of a specific supplemental food item which
9 exceeds the store's documented inventory of that supplemental food item for six or more days within
10 a 60-day period. The six or more days do not have to be consecutive days within the 60-day period.
11 Failure or inability to provide records or providing false records required under Item ~~(30)~~(32) of
12 Rule .0708 for an inventory audit shall be deemed a violation of 7 C.F.R. 246.12(l)(1)(iii)(B) and
13 this Subparagraph;
- 14 (2) two occurrences of vendor overcharging within a 12-month period;
- 15 (3) two occurrences of receiving, transacting or redeeming food instruments or cash-value vouchers
16 outside of authorized channels, including the use of an unauthorized vendor or an unauthorized
17 person within a 12-month period;
- 18 (4) two occurrences of charging for supplemental food not received by the WIC customer within a 12-
19 month period;
- 20 (5) two occurrences of providing credit or non-food items, other than alcohol, alcoholic beverages,
21 tobacco products, cash, firearms, ammunition, explosives, or controlled substances as defined in 21
22 U.S.C. 802, in exchange for food instruments or cash-value vouchers within a 12-month period; or
- 23 (6) three occurrences of providing unauthorized food items in exchange for food instruments or cash-
24 value vouchers, including charging for supplemental food provided in excess of those listed on the
25 food instrument within a 12-month period.

26 (b) Title 7 C.F.R. 246.12(l)(2)(i) is incorporated by reference with all subsequent amendments and editions. Except
27 as provided in 7 C.F.R. 246.12 (l)(1)(xii), a vendor shall be disqualified from the WIC Program for the following
28 state-established violations in accordance with the number of occurrences and sanctions set forth below:

- 29 (1) One year for two occurrences within a 12-month period of discrimination on the basis of WIC
30 participation as referenced in Item ~~(38)~~(40) of Rule .0708. Each date this violation is detected is a
31 separate occurrence;
- 32 (2) One year for three occurrences within a 12-month period of failure to properly transact a WIC food
33 instrument or cash-value voucher by not completing the date and purchase price on the WIC food
34 instrument or cash-value voucher before obtaining the WIC customer's signature, by not obtaining
35 the WIC customer's signature in the presence of the cashier, or by accepting a WIC food instrument
36 or cash-value voucher prior to the "Issue Date" or after the "Participant Must Use By" dates on the

- 1 food instrument or cash-value voucher. Except as provided in 7 C.F.R. 246.12(l)(3)(iv), each
2 improperly transacted food instrument or cash-value voucher is a separate occurrence;
- 3 (3) One year for three occurrences within a 12-month period of requiring a cash purchase to transact a
4 WIC food instrument or cash-value voucher. Except as provided in 7 C.F.R. 246.12(l)(3)(iv), each
5 transacted food instrument or cash-value voucher requiring a cash purchase is a separate occurrence;
- 6 (4) 270 days for three occurrences within a 12-month period of contacting a WIC customer in an attempt
7 to recoup funds for a food instrument or cash-value voucher or contacting a WIC customer outside
8 the store regarding the transaction or redemption of a WIC food instrument or cash-value voucher.
9 Each contact with any WIC customer is a separate occurrence, whether each contact is with the same
10 or different WIC customers;
- 11 (5) 180 days for three occurrences within a 12-month period of failure to provide program-related
12 records referenced in Item ~~(30)~~(32) of Rule .0708 when requested by WIC staff, except as provided
13 in Item ~~(30)~~(32) of Rule .0708 and Subparagraph (a)(1) of this Rule for failure or inability to provide
14 records for an inventory audit. Each request for records is a separate occurrence, whether each
15 request is for the same or different records;
- 16 (6) 180 days for three occurrences within a 12-month period of failure to provide the information
17 referenced in Item ~~(31)~~(33) of Rule .0708 when requested by WIC staff. Each request for
18 information is a separate occurrence, whether each request is for the same or different information;
- 19 (7) 180 days for three occurrences within a 12-month period of failure to stock the minimum inventory
20 specified in Item ~~(24)~~(25) of Rule .0708. Each date this violation is detected is a separate
21 occurrence;
- 22 (8) 90 days for three occurrences within a 12-month period of stocking WIC supplemental foods outside
23 of the manufacturer's expiration date. Each date this violation is detected is a separate occurrence;
- 24 (9) 90 days for three occurrences within a 12-month period of failure to allow monitoring of a store by
25 WIC staff. Each attempt to monitor the store is a separate occurrence;
- 26 (10) 90 days for five occurrences within a 12-month period of failure to submit a WIC Price List as
27 required by Item ~~(32)~~(34) of Rule .0708. Each written request by the state or local WIC agency for
28 submission of a WIC Price List is a separate occurrence, whether each request is for the same or
29 different WIC Price Lists;
- 30 (11) 60 days for three occurrences within a 12-month period of failure to mark the current shelf prices of
31 all WIC supplemental foods on the foods or have the prices posted on the shelf or display case. Each
32 date this violation is detected is a separate occurrence; and
- 33 (12) 60 days for five occurrences within a 12-month period of requiring the purchase of a specific brand
34 when more than one WIC supplemental food brand is available. Except as provided in 7 C.F.R.
35 246.12(l)(3)(iv), each transacted food instrument or cash-value voucher requiring the purchase of a
36 specific brand when more than one WIC supplemental food brand is available is a separate
37 occurrence.

1 If during the course of a single investigation the state agency determines that a vendor has committed multiple state-
2 established violations, the disqualification periods shall be cumulative, provided that the total period of
3 disqualification shall not exceed one year for state-established violations investigated as part of a single investigation,
4 as defined in Paragraph (c) of this Rule.

5 (c) For investigations pursuant to this Section, a single investigation is:

6 (1) Compliance buy(s) conducted by undercover investigators within a 12-month period to detect the
7 following violations:

- 8 (A) buying or selling food instruments or cash-value vouchers for cash (trafficking);
- 9 (B) selling firearms, ammunition, explosives, or controlled substances as defined in 21 U.S.C.
10 802, in exchange for food instruments or cash-value vouchers;
- 11 (C) selling alcohol or alcoholic beverages or tobacco products in exchange for food instruments
12 or cash-value vouchers;
- 13 (D) vendor overcharging;
- 14 (E) receiving, transacting, or redeeming food instruments or cash-value vouchers outside of
15 authorized channels, including the use of an unauthorized vendor or an unauthorized
16 person;
- 17 (F) charging for supplemental food not received by the WIC customer;
- 18 (G) providing credit or non-food items, other than alcohol, alcoholic beverages, tobacco
19 products, cash, firearms, ammunition, explosives, or controlled substances as defined in 21
20 U.S.C. 802, in exchange for food instruments or cash-value vouchers;
- 21 (H) providing unauthorized food items in exchange for food instruments or cash-value
22 vouchers, including charging for supplemental food provided in excess of those listed on
23 the food instrument;
- 24 (I) failure to properly transact a WIC food instrument or cash-value voucher;
- 25 (J) requiring a cash purchase to transact a WIC food instrument or cash-value voucher; or
- 26 (K) requiring the purchase of a specific brand when more than one WIC supplemental food
27 brand is available.

28 (2) Monitoring reviews of a vendor conducted by WIC staff within a 12-month period which detect the
29 following violations:

- 30 (A) failure to stock the minimum inventory specified in Item ~~(24)~~(25) of Rule .0708;
- 31 (B) stocking WIC supplemental food outside of the manufacturer's expiration date;
- 32 (C) failure to allow monitoring of a store by WIC staff;
- 33 (D) failure to provide program-related records referenced in Item ~~(30)~~(32) of Rule .0708 when
34 requested by WIC staff;
- 35 (E) failure to mark the current shelf prices of all WIC supplemental foods on the foods or have
36 the prices posted on the shelf or display case; or
- 37 (F) unauthorized use of the "WIC" acronym or the logo.

- (3) Any other method used by the state or local agency to detect the following violations by a vendor within a 12-month period:
- (A) failure to attend annual vendor training;
 - (B) failure to submit a WIC Price List as required by Item ~~(32)~~(34) of Rule .0708;
 - (C) discrimination on the basis of WIC participation as referenced in Item ~~(38)~~(40) of Rule .0708.
 - (D) contacting a WIC customer in an attempt to recoup funds for food instruments or cash-value vouchers or contacting a WIC customer outside the store regarding the transaction or redemption of WIC food instruments or cash-value vouchers;
 - (E) nonpayment of a claim assessed by the state agency;
 - (F) providing false, erroneous, or misleading information to the state or local WIC agency;
 - (G) claiming reimbursement for the sale of an amount of a specific supplemental food item which exceeds the store's documented inventory of that supplemental food item for a specific period of time, or failure or inability to provide records or providing false records required under Item ~~(30)~~(32) of Rule .0708 for an inventory audit;
 - (H) failure to purchase infant formula, exempt infant formula or WIC-eligible medical foods from the sources specified in Item (3) of Rule .0707; or
 - (I) providing WIC customers infant formula, exempt infant formula, or WIC eligible medical food that was not purchased from the sources specified in Item (3) of Rule .0707.
- (d) The SNAP disqualification provisions in 7 C.F.R. 246.12(l)(1)(vii) are incorporated by reference with all subsequent amendments and editions.
- (e) The participant access provisions of 7 C.F.R. 246.12(l)(1)(ix) and 246.12(l)(8) are incorporated by reference with all subsequent amendments and editions. The existence of any of the factors listed in Parts (f)(3)(A), (f)(3)(B) or (f)(3)(C) of this Rule shall conclusively show adequate participant access provided there is no geographic barrier, such as an impassable mountain or river, to using the other authorized WIC vendors referenced in these Parts. The agency shall not consider other indicators of inadequate participant access when any of these factors exist.
- (f) The following provisions apply to monetary and civil money penalties assessed in lieu of disqualification of a vendor:
- (1) The civil money penalty formula in 7 C.F.R. 246.12(l)(1)(x) is incorporated by reference with all subsequent amendments and editions, provided that the vendor's average monthly redemptions shall be calculated by using the six-month period ending with the month immediately preceding the month during which the notice of administrative action is dated.
 - (2) The state agency may also impose monetary penalties in accordance with G.S. 130A-22(c1) in lieu of disqualification of a vendor for the state-established violations listed in Paragraph (b) of this Rule when the state agency determines that disqualification of a vendor would result in participant hardship in accordance with Subparagraph (f)(3) of this Paragraph.

- (3) In determining whether to disqualify a WIC vendor for the state-established violations listed in Paragraph (b) of this Rule, the agency shall not consider other indicators of hardship if any of the following factors, which conclusively show lack of hardship, are found to exist:
- (A) the noncomplying vendor is located outside of the limits of a city, as defined in G.S. 160A-2, and another WIC vendor is located within seven miles of the noncomplying vendor;
 - (B) the noncomplying vendor is located within the limits of a city, as defined in G.S. 160A-2, and another WIC vendor is located within three miles of the noncomplying vendor; or
 - (C) a WIC vendor, other than the noncomplying vendor, is located within one mile of the local agency at which WIC participants pick up their food instruments or cash-value vouchers.
- (4) The provisions for failure to pay a civil money penalty in 7 C.F.R. 246.12(l)(6) are incorporated by reference with all subsequent amendments and editions. These provisions also apply to a vendor that fails to pay a monetary penalty imposed under G.S. 130A-22(c1).
- (g) The provisions of 7 C.F.R. 246.12(l)(1)(viii) prohibiting voluntary withdrawal from the WIC Program or nonrenewal of the WIC Vendor Agreement as an alternative to disqualification are incorporated by reference with all subsequent amendments and editions.
- (h) The provisions of 42 USC 1786 (f)(26) and 7 CFR 246.12(l)(3) regarding vendor notification of violations are incorporated by reference with all subsequent amendments and editions.
- (i) The state agency may offset payments to an authorized vendor if the vendor fails to reimburse the state agency in accordance with Item ~~(33)~~(35) of Rule .0708.
- (j) In accordance with 7 C.F.R. 246.12(l)(7) or 246.12(u)(5) or both, North Carolina's procedures for dealing with abuse of the WIC program by authorized WIC vendors do not exclude or replace any criminal or civil sanctions or other remedies that may be applicable under any federal or state law.
- (k) Notwithstanding other provisions of this Rule and Rules .0707 and .0708, for the purpose of providing a one-time payment to a non-authorized store for WIC food instruments or cash-value vouchers accepted by the store, an agreement for a one-time payment need only be signed by the store manager and the state agency. The store may request such one-time payment directly from the state agency. The store manager shall sign an agreement indicating that the store has provided foods as prescribed on the food instrument or as allowed with the cash-value voucher, charged current shelf prices or less than current shelf prices, not charged sales tax, and verified the identity of the WIC customer. Any agreement entered into in this manner shall automatically terminate upon payment of the food instruments or cash-value vouchers. After entering into an agreement for a one-time payment, a non-authorized store shall not be allowed to enter into any further one-time payment agreements for WIC food instruments or cash-value vouchers accepted thereafter.
- (l) Except as provided in 7 C.F.R. 246.18(a)(2), an authorized WIC vendor shall be given at least 15 days advance written notice of any adverse action which affects the vendor's participation in the WIC Program. The vendor appeal procedures shall be in accordance with 10A NCAC 43D .0800.

History Note: Authority G.S. 130A-361; 7 C.F.R. 246; 42 U.S.C. 1786;

1 *Eff. January 1, 2018;February 1, 2013,2013.*

2 *Effective January 1, 2018.*

3

4

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 43G .0108

DEADLINE FOR RECEIPT: Friday, December 8, 2017

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On the Submission for Permanent Rule form, Box 6, you published this Rule on March 1, 2017. In addition, when you published, you stated the hearing would be April 11, 2017. Assuming that is correct for this Rule, please make the corrections.

Also on the form, Box 8, when you published, you stated no fiscal note was required pursuant to G.S. 150B-21.3A(d)(2), but here you state it was approved by OSBM. Please review and make any necessary correction here.

Why do you need this Rule? What is not addressed by G.S. 130A-126?

§ 130A-126. Rule-making authority for birth - three-year-old early intervention program.

The rule-making authority for the birth - three-year-old early intervention program through Part C of the Individuals with Disabilities Act (IDEA) is transferred from the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services to the Commission for Public Health. (2005-276, s. 10.54A; 2007-182, s. 2.)

Is the intent to make it clear that the Department will administer the Commission's rules?

Assuming you need to retain it, is there a better citation to the law? Is it codified in the USC?

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

1 10A NCAC 43G .0108 is readopted with changes as published in 31:17 NCR 1753 as follows:

2
3 **10A NCAC 43G .0108 ADMINISTRATION**

4 The Department of Health and Human Services shall administer the statewide early intervention program under
5 Federal law, Part C of the Individuals with Disabilities Education Act (IDEA).

6
7 *History Note: Authority G.S. 130A-126;*

8 *Temporary Adoption Eff. July 1, 2006;*

9 *Adoption Eff. January 1, ~~2007, 2007;~~*

10 *Readopted Eff. January 1, 2018.*

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 43G .0110

DEADLINE FOR RECEIPT: Friday, December 8, 2017

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On the Submission for Permanent Rule form, Box 6, please complete the date of the hearing. The date you published was April 11, 2017.

Also on the form, Box 8, when you published, you stated no fiscal note was required pursuant to G.S. 150B-21.3A(d)(2), but here you state it was approved by OSBM. Please review and make any necessary correction here.

In (a), line 4, please capitalize "Subchapter"

On line 6 and elsewhere the term is used, what is the "Children's Developmental Services Agency"? Is this the agency in Rule 10A NCAC 43G .0109?

In (b)(1), line 10, please replace "is" with "shall"

Why does the list in (b)(1)(A) through (E) start with capital letters, when other lists begin with lowercase letters? Please be consistent here.

I take that your regulated public knows what the terms in (b)(1)(A) through (E) mean?"

In (b)(2), lines 19, 21, 23, and 25, please delete "above" or state "listed" or "stated" or "areas of development in Subparagraph (b)(1)"

In (b)(2)(A), on line 19, delete the "or" at the end of the line.

In (b)(2)(B), line 20, replace "which" with "that"

Line 21, change the comma after "development" to a semicolon.

In (b)(2)(D), line 24, replace "which" with "that"

In (c), line 26, replace "is" with "shall be"

On line 27, replace "which" with "that"

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

On line 27, what is a “high probability” and who determines it?

On line 27, is the diagnosis of the underlying condition or that the condition will create a high probability of developmental delay?

In (c)(1) through (c)(8), consider deleting “These are” and just stating “Children diagnosed...”

In (c)(6), Page 2, is this not fully correctable? If the child can have better, but still lower than average, sight through glasses, surgery, etc., would he or she not qualify?

In (c)(7), line 5, to be consistent, consider stating, “implications. Some examples are...” [See (c)(1) and (c)(2)]

Consider beginning (c)(8)(A) through (J) with lowercase letters.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

1 10A NCAC 43G .0110 is readopted as published in 31:17 NCR 1753 as follows:

2
3 **10A NCAC 43G .0110 ELIGIBILITY**

4 (a) Children from birth to age three are eligible for early intervention services under the provisions of this subchapter
5 and under Part C of the Individuals with Disabilities Education Act (IDEA) if they have been determined by the
6 Children's Developmental Services Agency to meet the criteria of one of the two following categories:

- 7 (1) developmental delay; or
8 (2) established conditions.

9 (b) Developmental Delay.

- 10 (1) A child is considered to have developmental delay if the child's development is delayed in one or
11 more of the following areas:

- 12 (A) Cognitive Development;
13 (B) Physical Development, including fine and gross motor function;
14 (C) Communication Development;
15 (D) Social-Emotional Development; or
16 (E) Adaptive Development.

- 17 (2) The specific level of delay shall be:

- 18 (A) documented by scores of 2.0 standard deviations below the mean of the composite score
19 (total test score) on standardized tests in at least one of the above areas of development; or
20 (B) documented by a 30 percent delay on instruments which determine scores in months in at
21 least one of the above areas of development, or
22 (C) documented by scores of 1.5 standard deviations below the mean of the composite score
23 (total test score) on standardized tests in at least two of the above areas of development, or
24 (D) documented by a 25 percent delay on instruments which determine scores in months in at
25 least two of the above areas of development.

26 (c) Established Conditions. A child is considered to have an established condition if the child has a diagnosed physical
27 or mental condition which has a high probability of resulting in developmental delay. Diagnosis may be made by
28 Children's Developmental Services Agency staff or the child's physician. Specific conditions through which a child
29 shall be deemed eligible in the established conditions category are as follows:

- 30 (1) Congenital Anomaly/Genetic Disorders/Inborn Errors of Metabolism. These are children diagnosed
31 with one or more congenital abnormalities or genetic disorders with developmental implications.
32 Some examples are Down Syndrome, Fragile X Syndrome, familial retardation syndromes, and fetal
33 alcohol syndrome.
34 (2) Congenital Infections. These are children diagnosed with congenital infections with developmental
35 implications. Some examples are toxoplasmosis, rubella, cytomegalovirus, and HIV.
36 (3) Autism. These are children diagnosed with autism or autism spectrum disorders.
37 (4) Attachment disorder. These are children with a diagnosed attachment disorder.

- (5) Hearing Loss. These are children diagnosed with unilateral or bilateral permanent hearing loss.
- (6) Visual Impairment. These are children diagnosed with a visual impairment that is not correctable with treatment, surgery, glasses, or contact lenses.
- (7) Neurologic Disease/Central Nervous System Disorders. These are children diagnosed with a disease or disorder known to affect the nervous system with developmental implications, such as Cerebral Palsy, Spina Bifida, Epilepsy, and Microcephaly.
- (8) Neonatal Conditions and Associated Complications. These are children diagnosed with one or more of the following neonatal diseases or disorders:
- (A) Gestational age less than 27 weeks or birth weight less than 1000 grams;
 - (B) Neonatal encephalopathy with neurological abnormality persisting at discharge from the neonatal intensive care unit.
 - (C) Moderate to Severe Ventricular Enlargement at discharge from the neonatal intensive care unit or a ventriculoperitoneal shunt;
 - (D) Neonatal seizures, stroke, meningitis, encephalitis, porencephaly, or holoprosencephaly;
 - (E) Bronchopulmonary Dysplasia requiring supplemental oxygen at discharge from the neonatal intensive care unit;
 - (F) Intrauterine Growth Retardation;
 - (G) Necrotizing enterocolitis requiring surgery;
 - (H) Abnormal neurological exam at discharge;
 - (I) Intraventricular hemorrhage III or IV; or
 - (J) Periventricular leukomalacia.

History Note: Authority G.S. 130A-126;
Temporary Adoption Eff. July 1, 2006;
Adoption Eff. January 1, ~~2007, 2007;~~
Readopted Eff. January 1, 2018.

REQUEST FOR TECHNICAL CHANGE

AGENCY: Commission for Public Health

RULE CITATION: 10A NCAC 43G .0111

DEADLINE FOR RECEIPT: Friday, December 8, 2017

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

On the Submission for Permanent Rule form, Box 6, please complete the date of the hearing. The date you published was April 11, 2017.

Also on the form, Box 8, when you published, you stated no fiscal note was required pursuant to G.S. 150B-21.3A(d)(2), but here you state it was approved by OSBM. Please review and make any necessary correction here.

In the Introductory Statement, please state "10A NCAC 43G .0111 is readopted..."

On line 4, do you need "Once a child is determined eligible for the program,"? Could you state "The Children's Developmental Services Agency shall develop a service plan for each eligible child based..."

On line 5, change "on" to "upon"

In Item (1), replace the comma with a semicolon.

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Amanda J. Reeder
Commission Counsel
Date submitted to agency: November 28, 2017

1 10A NCAC 43G .0110 is readopted as published in 31:17 NCR 1753 as follows:

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3 **10A NCAC 43G .0111 SERVICE PLAN – SERVICE DELIVERY**

4 Once a child is determined eligible for the program, the Children's Developmental Services Agency shall develop a
5 service plan based on the child's needs and the requirements of Part C of the Individuals with Disabilities Education
6 Act (IDEA). Service provision shall be monitored by the Children's Developmental Services Agency. The services
7 shall be provided by the following:

- 8 (1) staff of the Children's Developmental Services Agency, or
9 (2) agencies or individuals within the community who have executed a provider agreement with the
10 Children's Developmental Services Agency.

11 *History Note:* Authority G.S. 130A-126;
12 Temporary Adoption Eff. July 1, 2006;
13 Adoption Eff. January 1, ~~2007~~, 2007;
14 Readopted Eff. January 1, 2018.
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16