

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 26E .0602

DEADLINE FOR RECEIPT: Tuesday, October 11, 2022.

PLEASE NOTE: This request may extend to 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 email the reviewing attorney to inquire concerning the staff recommendation.

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

In your introductory statement, please delete "19" following "NCR".

In (a)(7), line 14, did you mean to exclude dispensers that might fall under the definition in G.S. 90-113.73(f)?

In (a)(8), line 15, did you mean to cite to G.S. 90-113.73(b), which contains the required information?

In (a)(8), line 16, by "system" do you mean "Controlled substance reporting system" as defined in (a)(1)?

In (a)(8), line 16, who must be affected by the "temporary electrical or technological failure"? The system, the user, or either?

In (a)(9)(a), lines 21-22, G.S. 90-113 was repealed in 1973. Please correct the citations here.

In (a)(9)(b), line 23, should "dose" be "does"?

In (a)(10), (11), and (12), please put quotes around the defined term.

In (a)(10), line 25 and (11), line 28, should "relationship" be capitalized?

In (a)(12), the entire item is unclear. I do not know what the defined term is, or what the definition is. Please revise for clarity.

Please delete the space between (a)(12) and (b) on line 34.

In your History Note, I do not understand the reference to G.S. 90-113.70, as this merely gives the short title of the North Carolina Controlled Substances Reporting System Act. Please correct or delete.

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

Brian Liebman
Commission Counsel
Date submitted to agency: September 26, 2022

1 **10A NCAC 26E .0602 is amended as published in 36:19 NCR 19 1530-1531 as follows:**

2
3 **10A NCAC 26E .0602 DEFINITIONS**

4 (a) As used in this Section, the following terms shall have the meanings as specified:

- 5 (1) "Controlled substance reporting system" means the reporting system as set forth in Article 5E of
6 Chapter 90.
- 7 (2) "ASAP" means the American Society for Automation in Pharmacy.
- 8 (3) "DEA" means the Drug Enforcement Administration responsible for enforcing the controlled
9 substances laws and regulations of the United States.
- 10 (4) "Delegate Account Holder" means a person designated to review records of the NC Controlled
11 Substance Reporting System with the written approval of the Master Account Holder.
- 12 (5) "DHHS" means North Carolina Department of Health and Human Services.
- 13 (6) "Dispense" means the same as defined in G.S. 90-87.
- 14 (7) "Dispenser" means the same as defined in G.S. 90-113.72.
- 15 (8) "Good faith" means an attempt to report the information required by G.S. 90-113.73(a) that was
16 unsuccessful due to the system not being operational due to a temporary electrical or technological
17 failure.
- 18 (9) "Master Account Holder" means a practitioner, as defined in G.S. 90-87, who has current DEA
19 registration.
- 20 (a) "Zero Reporting" means the following: instances when a dispenser who, except as
21 provider in G.S. 90-113(c) and (d), fails to comply with the reporting provisions of G.S.
22 90-113; or
- 23 (b) instances when a dispenser dose not dispense any Schedule II – IV controlled substances
24 during the previous business day.
- 25 (10) Pharmacist-patient relationship means a consensual relationship in which an individual seeks
26 pharmaceutical care from a pharmacist, and the pharmacist affirmatively acts to provide
27 pharmaceutical care, or agrees to do so.
- 28 (11) Prescriber-patient relationship means a consensual relationship in which an individual seeks
29 medical care from a prescriber, and the prescriber affirmatively acts to provide medical care, or
30 agrees to do so.
- 31 (12) Data Errors notification-error notifications related to data submission that are sent by the software
32 vendor of the dispenser that is required to report will be deemed to be a notice of error report to
33 the dispenser.

34
35 (b) Any term not defined in this Section shall have the same definitions as set forth in G.S. 90-87 and 90-113.72.

36
37 *History Note: Authority G.S. 90-113.70; 90-113.76;*

1 *Temporary Adoption Eff. January 1, 2007;*
2 *Eff. April 1, 2007;*
3 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February*
4 *2, ~~2016~~2016;*
5 *Amended Eff: November 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 26E .0604

DEADLINE FOR RECEIPT: Tuesday, October 11, 2022.

PLEASE NOTE: This request may extend to 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 email the reviewing attorney to inquire concerning the staff recommendation.

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

In general, why is (a) necessary? It appears only to re-state the requirements in G.S. 90-113.73(b), except it leaves out 90-113.73(b)(10a).

Assuming (a) is necessary, please end the last sentence in (a) on line 5 with a colon, end each item in the list with a semicolon, and put an "and" following the semi-colon at the penultimate item.

Please delete the comma in (a)(2)(a), line 9, following "number."

In (a)(2)(c), line 11, put "Birth" in lowercase.

In (a)(6), line 15, add "a" before "refill."

In (b), line 22, place a comma following "submission".

*I am a little confused by the interplay between (c) and (d). In (c), you direct a dispenser to correct errors and "resubmit" required information within 10 calendar days. As (c) does not specify, I assume a dispenser would "resubmit" via the CSRS. However, in (d), you direct the dispenser to "correct the reporting error via the CSRS website" **or** to resubmit the report.*

Please clarify how a dispenser is to correct an error once it receives notification from DHHS.

In particular, if there is a distinction between "correct[ing] via" the CSRS website and "resubmitting" a report, please provide a link to the relevant webpage where one would make the correction.

Brian Liebman
Commission Counsel
Date submitted to agency: September 26, 2022

Also, with respect to (c) and (d), what happens if the dispenser catches the error before DHHS does? How is the dispenser to make the correction?

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

Brian Liebman
Commission Counsel
Date submitted to agency: September 26, 2022

1 **10A NCAC 26E .0604 is adopted as published in 36:19 NCR 1531 as follows:**

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3 **10A NACA 26E .0604 REPORTING REQUIREMENTS**

4 (a) Each dispenser shall report the following information to the Controlled-Substances Reporting System in
5 accordance with the time frames provided in G.S. 90-113.73.

6 (1) The dispenser's DEA number.

7 (2) The name of the patient for whom the controlled substance is being dispensed as well as the
8 patient's:

9 (a) Full address including apartment number, where applicable, city, state, and zip code;

10 (b) Telephone number; and

11 (c) Date of Birth.

12 (3) The date the prescription was written.

13 (4) The date the prescription was filled.

14 (5) The prescription number.

15 (6) Whether the prescription is new or refill.

16 (7) The metric quantity of the drug dispensed.

17 (8) The estimated days of supply of the dispensed drug, if provided to the dispenser.

18 (9) The national drug code of the dispensed drug.

19 (10) The prescriber's DEA number.

20 (11) The method of payment for the prescription.

21 (b) DHHS shall notify the dispenser of failure to report data as required by G.S. 90-113.73 and any reporting errors
22 related to that submission in writing, within ten business days of detecting the error.

23 (c) The dispenser shall correct the error(s) and resubmit the required information within ten calendar days of the
24 date of the written notification.

25 (d) The dispenser shall correct the reporting error via the CSRS website or by resubmitting the report itself.

26
27 *History Note: Authority G.S. 90-113.73;*

28 *Eff. November 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 26E .0605

DEADLINE FOR RECEIPT: Tuesday, October 11, 2022.

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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 email the reviewing attorney to inquire concerning the staff recommendation.

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

In general to the Rule, are (a) and (b) cumulative? In (a) it says that DHHS shall consider these factors for anyone who violates Ch. 90, Art. 5E, which includes the reporting requirements in G.S. 90-113.73(e). Thus, if DHHS is imposing a penalty for failure to report pursuant to 90-113.73(e), must it consider the (a) factors along with the (b) factors?

In (a)(1), line 6, the use of the term "including" has an open-ended context indicating there is more to be considered than what is explicitly mentioned. If it doesn't change the meaning, I would consider "particularly" here.

In (a)(2), lines 8-9, consider revising in the active tense. For example: "whether the person succeeded in improperly obtaining..."

In (a)(3), line 10, aren't "intentionally, knowingly, and negligently" the levels of intent mentioned in the statute? What are you referring to by "including"? As I mentioned earlier, including has an open-ended connotation.

In your History Note, please add a reference to G.S. 90-113.73.

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

Brian Liebman
Commission Counsel

Date submitted to agency: September 26, 2022

1 **10A NCAC 26E .0605 is adopted as published in 36:19 NCR 1531 as follows:**

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3 **10A NCAC 26E .0605 PENALTIES**

4 (a) DHHS shall consider the following factors in determining the amount of each civil penalty assessed against a
5 person who violates Chapter 90, Article 5E:

6 (1) the type of violation including whether it involved an improper attempt to obtain or release
7 information from the CSRS;

8 (2) whether the violation involved success in improperly obtaining or releasing information from the
9 CSRS;

10 (3) the level of intent evident in the violation including whether it was done intentionally, knowingly,
11 or negligently;

12 (4) the frequency of the violations the person has committed; and

13 (5) the number of violations the person has committed.

14 (b) DHHS shall consider the following factors in determining the amount of civil penalty assessed against a
15 pharmacy that employs dispensers who fail to report information in accordance with G.S. 90-113.73(e):

16 (1) whether it is a first, second, third, or subsequent violation within a calendar year;

17 (2) whether it is a continuing violation;

18 (3) whether the pharmacy has acted in good faith in attempting to report the required information.

19
20 *History Note: Authority G.S. 90-113.75;*

21 *Eff. November 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 27G .0207

DEADLINE FOR RECEIPT: Tuesday, October 11, 2022.

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

In (a), line 4, what does "area-wide" mean?

In (a), line 5, please define or delete "appropriate".

In (b), line 6, you refer to "the plan" in the singular, but reference "a written fire plan" and an "area-wide disaster plan" in (a). Please either change to "plans" or indicate which plan must be made available to staff.

In (b), line 6, are the evacuation procedures and routes part of either of the plans in (a)? Please clarify.

In (c), lines 7-8, what are "conditions that simulate fire emergencies"? Please clarify what you're requiring.

In (d), line 9, what are "basic" first aid supplies? Please clarify what you're requiring.

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

Brian Liebman
Commission Counsel

Date submitted to agency: September 26, 2022

1 **10A NCAC 27G .0207 is readopted as published in 36:19 NCR 1532 as follows:**

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3 **10A NCAC 27G .0207 EMERGENCY PLANS AND SUPPLIES**

4 (a) Each facility shall develop a written fire plan and area-wide disaster plan and shall make a copy of these plans available
5 to the appropriate county emergency services agency, upon request.

6 (b) The plan shall be made available to all staff and evacuation procedures and routes shall be posted in the facility.

7 (c) Fire and disaster drills in a 24-hour facility shall be held at least quarterly and shall be repeated for each shift. Drills shall
8 be conducted under conditions that simulate fire emergencies.

9 (d) Each facility shall have basic first aid supplies accessible for use.

10

11 *History Note: Authority G.S. 122C-26; 143B-147;*

12 *Eff. May 1, 1996;*

13 *Recodified from 10 NCAC 14V .0205 to 10 NCAC 14V .0207 Eff January 3, ~~2001-2001~~;*

14 *Readopted Eff. November 1, 2022.*

REQUEST FOR CHANGES PURSUANT TO G.S. 150B-21.10

AGENCY: Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services

RULE CITATION: 10A NCAC 27G .2202

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

In (b), line 5, what is a “center”?

In (b), line 5, what do you mean by “experience” in developmental disabilities? How much are you requiring?

In (b), line 6, what is a “related field”? Please define.

In (b), line 6, add the oxford comma after “psychology”.

In (b), line 7, what do you mean by “comparable” experience and education? Comparable to what?

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

Brian Liebman
Commission Counsel

Date submitted to agency: September 26, 2022

1 **10A NCAC 27G .2202 is readopted as published in 36:19 NCR 1532 as follows.**

2

3 **10A NCAC 27G .2202 STAFF**

4 (a) Each staff member, except student trainees and supervised volunteers, shall be at least 18 years of age.

5 (b) Each center shall have a designated program director who has experience in developmental disabilities, and holds a
6 baccalaureate degree with specialization in administration, education, social work, nursing, psychology or a related field or
7 have comparable experience and education.

8 (c) A minimum of two staff members shall provide direct child care at all times.

9 (d) A minimum of one direct care staff member shall be on duty for every five clients.

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11 *History Note: Authority G.S. 122C-26; 143B-147;*

12 *Eff. May 1, ~~1996~~1996;*

13 *Readopted Eff. November 1, 2022*