

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

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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.

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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.

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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.*

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.

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

28 *Eff. November 1, 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.

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

21 *Eff. November 1, 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.

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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.*

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

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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*