

1 10A NCAC 26E .0602 is amended with changes as published in 36:19 NCR 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~~"**system (CSRS)**" means the reporting system as set forth
6 in Article 5E of 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] CSRS 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,] 90-113.72 and 90-113.73(f).
- 15 (8) "Good faith" means an attempt to report the information required by G.S. [90-113.73(a)]90-
16 113.73(b) that was unsuccessful due to [the system not being operational due to]a temporary
17 electrical or technological [failure.]failure impacting the transmission of data to the CSRS.
- 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]provided in G.S. [90-113(e) and (d),]90-113.73(c) and (d), fails to comply with
22 the reporting provisions of G.S. 90-113;90-113.73; or
- 23 (b) instances when a dispenser [dose]does not dispense any Schedule II – IV controlled
24 substances during the previous business day.
- 25 (10) [Pharmacist-patient relationship] "Pharmacist-patient Relationship" means a consensual
26 relationship in which an individual seeks pharmaceutical care from a pharmacist, and the
27 pharmacist affirmatively acts to provide pharmaceutical care, or agrees to do so.
- 28 (11) [Prescriber-patient relationship] "Prescriber-patient Relationship" means a consensual relationship
29 in which an individual seeks medical care from a prescriber, and the prescriber affirmatively acts
30 to provide medical care, or agrees to do so.
- 31 (12) [Data Errors notification-error notifications]"Data Errors Notification" means a written
32 notification from DHHS to a dispenser of failure to report data as required by G.S. 90-113.73 and
33 of errors related to the submission of that data. Errors occur when information required per Rule
34 10A NCAC 26E .0604(a) is omitted, incomplete, or submitted late.[related to data submission that
35 are sent by the software vendor of the dispenser that is required to report will be deemed to be a
36 notice of error report to the dispenser.]

37 (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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*History Note: Authority G.S. ~~90-113.70~~; 90-113.76;
Temporary Adoption Eff. January 1, 2007;
Eff. April 1, 2007;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February
2, ~~2016~~, 2016;
Amended Eff: November 1, 2022.*

1 10A NCAC 26E .0604 is adopted with changes 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~~ **Controlled Substances**
5 Reporting System in accordance with the time frames provided in G.S. ~~90-113.73~~ **90-113.73**:

- 6 (1) ~~The~~ **the** dispenser's DEA ~~number~~ **number**;
- 7 (2) ~~The~~ **the** name of the patient for whom the controlled substance is being dispensed as well as the
8 patient's:
 - 9 (a) ~~Full~~ **full** address including apartment ~~number~~ **number** where applicable, city, state, and zip
10 code;
 - 11 (b) ~~Telephone~~ **telephone** number; and
 - 12 (c) ~~Date~~ **date** of ~~Birth~~ **birth**;
- 13 (3) ~~The~~ **the** date the prescription was ~~written~~ **written**;
- 14 (4) ~~The~~ **the** date the prescription was ~~filled~~ **filled**;
- 15 (5) ~~The~~ **the** prescription ~~number~~ **number**;
- 16 (6) ~~Whether~~ **whether** the prescription is new or ~~a refill~~ **refill**;
- 17 (7) ~~The~~ **the** metric quantity of the drug ~~dispensed~~ **dispensed**;
- 18 (8) ~~The~~ **the** estimated days of supply of the dispensed drug, if provided to the ~~dispenser~~ **dispenser**;
- 19 (9) ~~The~~ **the** national drug code of the dispensed ~~drug~~ **drug**;
- 20 (10) ~~The~~ **the** prescriber's DEA ~~number~~ **number**;
- 21 ~~(11)~~ **(12)** ~~the prescriber's national provider identification number, for any prescriber that has one provided,~~
22 ~~however, a pharmacy shall not be subject to a civil penalty under G.S. 90-113.73(e) for failure to~~
23 ~~report the prescriber's national provider identification number when it is not received by the~~
24 ~~pharmacy; and~~
25 ~~(11)~~ **(12)** ~~The~~ **the** method of payment for the prescription.

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

28 (c) The dispenser shall correct the error(s) and resubmit the required ~~information~~ **information**, via his or her
29 ~~dispensation software~~ **dispensation software**, within ten calendar days of the date of the written notification.

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

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32 *History Note: Authority G.S. 90-113.73;*
33 *Eff. November 1, 2022.*

1 10A NCAC 26E .0605 is adopted with changes 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~~ the violation involved an improper attempt to obtain or
7 release information from the CSRS;

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

10 (3) ~~the level of intent evident in the violation including whether it was done~~ the person committed the
11 violation intentionally, knowingly, 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~~ these additional factors in determining the amount of civil penalty assessed
15 against a 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; 90-113.73; 90-113.75;~~

21 *Eff. November 1, 2022.*

1 10A NCAC 27G .0207 is readopted with changes 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
5 available to the **appropriate** county emergency services **agency, agencies** upon request. **The plans shall include**
6 **evacuation procedures and routes.**

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

8 (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
9 be conducted under conditions that simulate **the facility's response to** fire emergencies.

10 (d) Each facility shall have **basica** first aid **supplies/kit** accessible for use.

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

13 *Eff. May 1, 1996;*

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

15 *Readopted Eff. November 1, 2022.*

1 10A NCAC 27G .2202 is readopted with changes 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/facility shall have a designated program director who has experience in working with individuals
6 diagnosed with developmental disabilities, and holds a baccalaureate degree with specialization in administration,
7 education, social work, nursing, psychology/psychology, or a related human services field/field or have comparable
8 experience and education.

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

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

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

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

14 *Readopted Eff. November 1, ~~2022~~ 2022.*