



NOTICE OF TEXT

[Authority G.S. 150B-21.2(c)]

OAH USE ONLY

VOLUME: 36

ISSUE: 19

CHECK APPROPRIATE BOX:

- Notice with a scheduled hearing
- Notice without a scheduled hearing
- Republication of text. Complete the following cite for the volume and issue of previous publication, as well as blocks 1 - 4 and 7 - 14. If a hearing is scheduled, complete block 5.
Previous publication of text was published in Volume: Issue:

1. Rule-Making Agency: [Commission for Mental Health/DD/SAS](#)

2. Link to agency website pursuant to G.S. 150B-19.1(c): <https://www.ncdhhs.gov/divisions/mental-health-developmental-disabilities-and-substance-abuse/commission-mhddsas/proposed-rules>

3. Proposed Action -- Check the appropriate box(es) and list rule citation(s) beside proposed action:

- ADOPTION:** [10A NCAC 26E .0604-.0605](#)

- AMENDMENT:** [10A NCAC 26E .0602](#)

- REPEAL:**

- READOPTION with substantive changes:**

- READOPTION without substantive changes:**

- REPEAL through READOPTION:**

4. Proposed effective date: [11/01/2022](#)

5. Is a public hearing planned? [No](#)

If yes:

Date	Time	Location

6. If no public hearing is scheduled, provide instructions on how to demand a public hearing:
 An agency must hold a public hearing on a rule it proposes to adopt if the agency publishes the text of the proposed rule in the North Carolina Register and the agency receives a written request for a public hearing on the proposed rule within 15 days after the notice of text is published. A request for a public hearing must be submitted in writing to dmhddsarules@dhhs.nc.gov.

7. Explain Reason For Proposed Rule(s):

The Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services (Commission) proposes to amend Rule 10A NCAC 26E .0602, Definitions, to incorporate additional definitions regarding the controlled substances reporting system. The Commission proposes to adopt Rule 10A NCAC 26E .0604, Reporting Requirements, to make clear the information that must be reported to the Controlled Substances Reporting System (CSRS) and to identify the time frames for notifying dispensers of reporting errors and that governing the dispenser's correction of the same. Rule 10A NCAC 26E .0605, Penalties, is proposed for adoption to provide notice of the factors DHHS must consider in assessing a penalty against those in violation of Chapter 90, Article 5E of the NC General Statutes.

8. Procedure for Subjecting a Proposed Rule to Legislative Review: If an objection is not resolved prior to the adoption of the rule, a person may also submit written objections to the Rules Review Commission. If the Rules Review Commission receives written and signed objections in accordance with G.S. 150B-21.3(b2) from 10 or more persons clearly requesting review by the legislature and the Rules Review Commission approves the rule, the rule will become effective as provided in G.S. 150B-21.3(b1). The Commission will receive written objections until 5:00 p.m. on the day following the day the Commission approves the rule. The Commission will receive those objections by mail, delivery service, hand delivery, or email. If you have any further questions concerning the submission of objections to the Commission, please call a Commission staff attorney at 984-236-1850.

Rule(s) is automatically subject to legislative review. Cite statutory reference:

9. The person to whom written comments may be submitted on the proposed rule(s):

Name: [W. Denise Baker](#)
Address: [3001 Mail Service Center](#)
[Raleigh, NC 27699-3001](#)
Phone (optional):
Fax (optional):
EMail (optional)

10. Comment Period Ends: [05/31/2022](#)

11. Fiscal impact. Does any rule or combination of rules in this notice create an economic impact? Check all that apply.

[State funds affected](#)
[Approved by OSBM](#)

12. Rule-making Coordinator:

Name: [Denise Baker](#)
[919-715-2095](#)
denise.baker@dhhs.nc.gov

Agency contact, if any:

Name:
Phone:
Email:

13. The Agency formally proposed the text of this rule(s) on

Date: [02/24/2022](#)

1 **10A NCAC 26E .0602 IS PROPOSED FOR AMENDMENT 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.

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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 **RULE 10A NCAC 26E .0604 IS PROPOSED FOR ADOPTION 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.*

1 **RULE 10A NCAC 26E .0605 IS PROPOSED FOR ADOPTION AS FOLLOWS**

2
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.*