

Draft Fiscal Note: Proposed Amendment and Adoption of Controlled Substance Reporting System Rules

Rule Citations: 10A NCAC 26E .0602, 10A NCAC 26E .0604, 10A NCAC 26E .0605
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Impact Summary:

Federal Government	None
State Government:	Yes
Local Government:	None
Substantial Economic Impact:	No
Pharmacies	Yes

Authority: G.S. §§ 90-113.70; 90-113.73, 90 113.75, 90-113.76; S.L. 2017-74, Sec. 10

I. Overview

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.

II. Rationale for Proposed Rule Amendment

The proposed rules changes implement the requirements of S.L. 2017-74, Sec. 10 which governs the time frame in which dispensers must report information to the CSRS and mandates the Commission to adopt rules to include factors DHHS must consider in assessing penalties against a pharmacy. The CSRS is an electronic database that tracks dispensed controlled substances prescriptions in the state. It is used by practitioners to help identify a patient that may be at risk of dependency or misuse of prescribed medications. It is a key strategy in the state and national program to address the opioid crisis. Since clinical decisions are made using the data in the system, it is essential that the data reported is timely and accurate. It is anticipated that these rules will increase compliance with CSRS reporting requirements and minimize reporting errors.

III. Analysis of Fiscal Impact

There are currently 2.5 FTEs that support these rules, 2 FTEs and .5 contractor. The FTEs work solely on the operation of the system and associated customer services which are necessary precursors to enacting the rules. This includes system maintenance, approving system user registration, monitoring pharmacy error reports, managing the pharmacy error reporting and notification process, monitoring the performance of the 24/7 customer services hotline, and responding to emailed requests for user assistance. The current base salary for the 2 FTEs is \$155,448. Assuming 7.65% of salary for social security benefits, 21.68% for retirement and an additional \$6,326 for medical, the total compensation for both FTEs is close to \$151,000. The .5 FTE is filled by a contractor with an annual salary of \$47,778, resulting in a total salary and fringe cost of \$199,680. See Table 1 below.

Table 1. Estimated Impact on State Government

There are no additional costs to reporting entities. The legislation to report to the CSRS has been in place since 2017 and have been reporting regularly into the system since that time. These rules are being established at the point that we know that this is standard business practice for reporting entities.

Estimated Costs	FY 2021-22	FY 2022-23	FY 2023-24	FY 2024-25	FY 2025-26
<i>CSRS Team Coordinator</i>					
Salary*	\$ 48,389	\$49,356.78	\$50,343.92	\$51,350.79	\$ 52,377.81
Social Security	\$ 3,702	\$ 3,775.79	\$ 3,851.31	\$ 3,928.34	\$ 4,006.90
Retirement	\$ 10,491	\$ 10,701	\$ 10,915	\$ 11,133	\$ 11,356
Medical	\$ 6,326	\$ 6,326	\$ 6,326	\$ 6,326	\$ 6,326
Compensation	\$ 68,907	\$ 70,159	\$ 71,436	\$ 72,738	\$ 74,066
<i>CSRS Business Lead</i>					
Salary*	\$ 59,281	\$60,466.62	\$61,675.95	\$62,909.47	\$ 64,167.66
Social Security	\$ 4,535	\$ 4,625.70	\$ 4,718.21	\$ 4,812.57	\$ 4,908.83
Retirement	\$ 12,852	\$ 13,109	\$ 13,371	\$ 13,639	\$ 13,912
Medical	\$ 6,326	\$ 6,326	\$ 6,326	\$ 6,326	\$ 6,326
Compensation	\$ 82,994	\$ 84,527	\$ 86,092	\$ 87,687	\$ 89,314
<i>Controlled Substances Consultant Specialist</i>					
Compensation	\$ 47,778	\$ 47,778	\$ 47,778	\$ 47,778	\$ 47,778
Total Compensation	\$ 199,680	\$ 202,465	\$ 205,305	\$ 208,203	\$ 211,158

*The base salary is assumed to increase by 2% in the following four years, we are assuming 0% increase for the .5 contractor.

System Misuse:

As of September 2021, there are 67,324 registered users. Based on the last 3 years historical data, we anticipate 4 users will misuse data which is very minimal. At a projected penalty amount of \$5,000 per incident, the annual amount of penalty assessed for system misuse is \$20,000. See Table 2 below. The system itself contains several automated processes and reminders of a user’s responsibility regarding use. Publishing rules on the process of deciding the penalties described in § 90-113.75. will clarify the process for individuals and organizations found in violation and reduce legal costs for both entity and state, in addition to creating an incentive for process changes to avoid repeat violations.

Table 2. System Misuse Penalty

Account Group	Registered Users (Sept21)
Admin	10
Dispenser	13,010
Dispenser Delegate	871
Law Enforcement	63
Other	285
Prescriber	43,170
Prescriber Delegate	9,903
Prescriber, Dispenser	12
	67,324
<i>Anticipated # of users to MISUSE data</i>	4
<i>Estimated penalty amount per incident</i>	\$ 5,000
<i>Estimated total penalty amount assessed</i>	\$ 20,000

Delinquent Pharmacies:

During SFY 2021, there were a total of 3,845 delinquent pharmacies. 3,715 were in Violation 1, 567 in violation 2 and 99 with Violation 3. Per GS 90-113.73, the civil penalty for each violation is no more than \$100 for a first violation, \$250 for a second violation, and \$500 for each subsequent violation, up to a maximum of \$5000 per pharmacy per calendar year. For purpose of this fiscal note, we are using the maximum civil penalty amount and estimated the total penalty per year to be \$562750. The penalty is expected to effectively deter delinquency and improve internal processes to prevent future delinquency in reporting agencies due to there being no other recourse in current legislation. See Table 3 below.

Table 3. Delinquent pharmacies

YrMo	Delinquent Pharmacies	Violation 1	Violation 2	Subsequent violations
Jul-20	214	204	43	4
Aug-20	161	153	35	2
Sep-20	330	322	88	1
Oct-20	622	615	41	5
Nov-20	249	242	32	4
Dec-20	232	225	56	8
Jan-21	218	211	48	14
Feb-21	149	142	32	3
Mar-21	141	134	20	1
Apr-21	641	634	30	2
May-21	194	173	59	28
Jun-21	313	294	41	11
Jul-21	381	366	42	16
Total	3845	3715	567	99

Civil Penalty	\$ 100	\$ 250	\$ 500
Civil Penalty Assessed	\$ 371,500	\$ 141,750	\$ 49,500
Total			\$ 562,750

Table 4. Total Impact

The penalties are expected to greatly reduce violations from occurring, by demonstrating a commitment by the state to act against violations and clarifying what those actions will be. A review of current levels of violations by pharmacies indicates that most are the result of preventable human error and process management. Violations related to access to the system are less common but performed despite the presence of reminders and warnings on the laws regarding use that automatically appear within different access points of the system. Providers who regularly use the CSRS in everyday practice are strong supporters of the availability of the data it provides. The Centers for Disease Control and Prevention (CDC), the Substance Abuse and Mental Health Administration (SAMSHA) and the Centers for Medicaid and Medicare Services (CMS) cite the use of systems such as the CSRS as essential to reducing the adverse effects of prescription drug misuse, including the reduction of opioid related overdoses. The system achieves these reductions by providing prescribers and pharmacists with up-to-date information on the number of prescriptions of controlled substances that have already been dispensed to a patient. This information effectively indicates if someone is on a combination of prescriptions that put them at higher risk for misuse, for overdose, or reveal patterns that indicate someone is actively seeking multiple prescriptions for reasons other than their health status (e.g., doctor shopping). Therefore, it is essential that the information reported into the system is current, accurate and reliable.

Although the rule amendments are expected to reduce future violations by strengthening enforcement, the magnitude of the rules' effect on compliance is unknown. Therefore, it is not possible to estimate the value of the expected benefits from reduced violations and improved patient outcomes from accurate and reliable data. Of the impacts that *can* be quantified, CRCS users will incur penalties estimated at \$583,000 per year; these

same penalties will be a benefit to state government in the form of additional revenue. The state will incur approximately \$200,000 per year in staff time costs to implement the rules.

		FY22	FY23	FY24	FY25	FY26
COSTS						
State Gov	State Government Staff Time	\$199,680	\$202,465	\$205,305	\$208,203	\$211,158
Users	System Misuse Penalty	\$20,000	\$20,000	\$20,000	\$20,000	\$20,000
	Delinquent Pharmacies	\$562,750	\$562,750	\$562,750	\$562,750	\$562,750
BENEFITS						
State Gov	Penalty Collections	\$582,750	\$582,750	\$582,750	\$582,750	\$582,750
Users	Savings from Reduced Violations			Unquantified		
NET IMPACT		\$(199,680)	\$(202,465)	\$(205,305)	\$(208,203)	\$(211,158)
		+ Unquantified Savings from Reduced Future Violations				
Net Present Value (2021 dollars), 7% Discount Rate		\$(199,680)	\$(189,220)	\$(179,321)	\$(169,956)	\$(161,091)

Appendix

**Proposed Amendment of
Rule 10A NCAC 26E .0602, *Definitions***

**Proposed Adoption of
Rule 10A NCAC 26E .0604, *Reporting Requirements*
Rule 10A NCAC 26E .0605, *Penalties***

1 **RULE 10A NCAC 26E .0602 IS PROPOSED FOR AMENDMENT 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" (CSRS) means the reporting system as set forth in Article
6 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) "Data Error Report" means a report issued by the Department notifying a dispenser of an error in
11 reporting, or failing to report, data to the CSRS.
- 12 (5) "Delegate Account Holder" means a person designated to review records of the NC Controlled
13 Substance Reporting System with the written approval of the Master Account Holder.
- 14 (6) "Dispense" means the same as defined in G.S. 90-87.
- 15 (7) "Dispenser" means the same as defined in G.S. 90-113.72.
- 16 (8) "Master Account Holder" means a practitioner, as defined in G.S. 90-87, who has current DEA
17 registration.
- 18 (9) Pharmacist-patient relationship means a consensual relationship in which an individual seeks
19 pharmaceutical care from a pharmacist, and the pharmacist affirmatively acts to provide
20 pharmaceutical care, or agrees to do so.
- 21 (10) Prescriber-patient relationship means a consensual relationship in which an individual seeks medical
22 care from a prescriber, and the prescriber affirmatively acts to provide medical care, or agrees to do
23 so.
- 24 (11) "Zero Reporting" means the following:
25 (a) instances when a dispenser who, except as provider in G.S. 90-113(c) and (d), fails to comply
26 with the reporting provisions of G.S. 90-113; or
27 (b) instances when a dispenser dose not dispense any Schedule II – IV controlled substances during
28 the previous business day.

29
30 (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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32 *History Note: Authority G.S. 90-113.70; 90-113.76;*
33 *Temporary Adoption Eff. January 1, 2007;*
34 *Eff. April 1, 2007;*
35 *Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2,*
36 *2016*
37 *Amended Eff. _____.*

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 date
24 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. XXXX;*

1 **RULE 10A NCAC 26E .0605 IS PROPOSED FOR ADOPTION 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 committed; and

13 (5) the number of violations committed.

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

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. XXXX*

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