Fiscal Note: Proposed Adoption of Rule 10A NCAC 27G .3505

Rule Citation:	**10A NCAC 27G .3605, Medication Units and Mobile Units**
Commission:	Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services
Agency Contact:	Denise Baker, Rulemaking Coordinator NC DHHS, Commission for MH/DD/SAS Phone: 984-236-5272; Email: denise.baker@dhhs.nc.gov

Impact Summary:	Federal Government:	No
	State Government:	Yes
	Local Government:	Possible indirect benefits
	Substantial Economic Impact:	No
	Provider Community:	Yes, although participation is voluntary.

Authority: G.S. 122C-35, 42 C.F.R. 8.12

Rationale for Proposed Rule Adoption

G.S. § 122C-35 directs the Commission for Mental Health, Developmental Disabilities, and Substance Abuse Services (hereinafter referred to as "Commission") to adopt emergency, temporary, and permanent rules for the licensure, inspection, and operation of Opioid Treatment Program (OTP) Medication Units and OTP Mobile Units, including rules concerning any of the following:

(1) Compliance with all applicable Substance Abuse and Mental Health Services Administration and federal Drug Enforcement Agency regulations governing opioid treatment program mobile units and opioid treatment program medication units;
(2) Identification of the location of opioid treatment program medication units and opioid treatment program mobile units;
(3) Schedules for the days and hours of operation to meet client needs;
(4) Maintenance and location of records;
(5) Requisite clinical staff and staffing ratios to meet immediate client needs at each opioid treatment program medication unit or opioid treatment program mobile unit, including client needs for nursing, counseling, and medical care;
(6) Emergency staffing requirements to ensure service delivery;
(7) Criteria for policies and procedures for clinical and individualized assessments of individuals to receive services at an opioid treatment program medication unit or opioid treatment program mobile unit that consider medical and clinical appropriateness and accessibility to individuals served;
(8) Number of clients allowed per opioid treatment program medication unit and opioid treatment program mobile unit, based on staffing ratios;

(9) Criteria to ensure the opioid treatment program facility is providing the required counseling to individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit; and
(10) Criteria for the opioid treatment program facility to ensure that individuals receiving services at an opioid treatment program medication unit or opioid treatment program mobile unit receive medical interventions when necessary (2023-65, x.10.2).

The Commission adopted Rule 10A NCAC 27G .3605 via emergency and temporary procedures effective September 16, 2024, and January 2, 2025, respectively. The Commission is now proposing to adopt the aforementioned Rule via permanent procedures. A copy of the proposed permanent rule is attached.

There is an urgency to this rule in order to provide enhanced response to the opioid epidemic, to reach populations who may not otherwise be able to access care – including rural and historically marginalized populations – and to better engage North Carolinians in safe, comprehensive, and evidence-based treatment for opioid use disorder.

Background

In July 2021, the federal Drug Enforcement Administration published its final rule allowing OTPs, authorized to dispense methadone for opioid use disorder, to add a "mobile component" to their existing Drug Enforcement Agency (DEA) registration – eliminating the separate registration requirement for the mobile component of OTPs. This streamlined registration process is intended to make it easier for OTPs to provide needed services in remote or underserved areas. The DEA took this action in response to the ongoing opioid crisis and the loss of tens of thousands of Americans per year to opioid-involved overdoses. This improved access was intended to reduce overdose deaths by increasing access to medications for opioid use disorder and by making treatment options available to anyone in need of them, anywhere in the country. In September 2021, SAMHSA released guidance on mediation units and mobile units and on the expansion of allowable services that an OTP could offer in these extension locations. In February 2024, 42 C.F.R., part 8 was published, which included updated requirements pertaining to Medication Units and Mobile Units. The revised Federal rule and subsequent guidelines on the establishment of services at medication units and mobile units incorporates allowances for all OTP services to be provided at these medication units and mobile units, as long as space and privacy permits. The final rule was effective April 2, 2024, and had a compliance date of October 2, 2023.

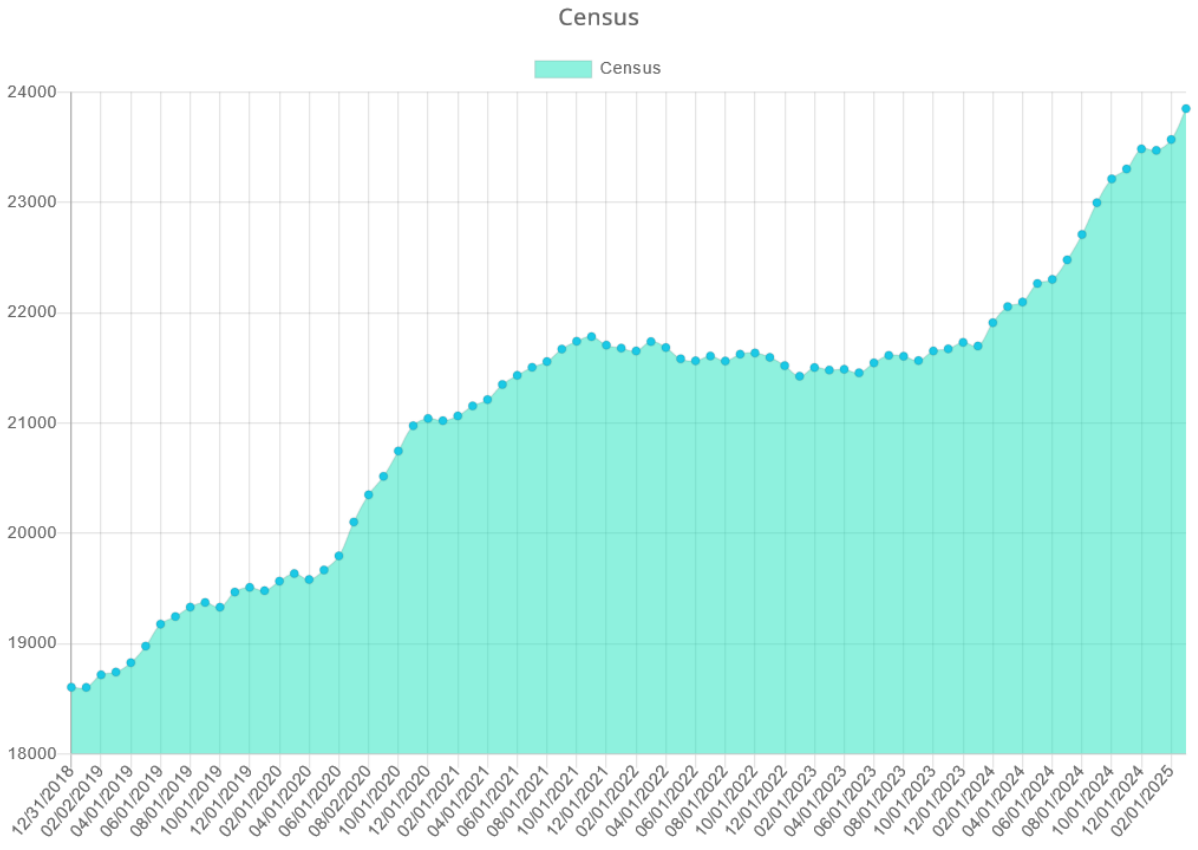
Medication Units and Mobile Units are self-contained components of an OTP facility. The proposed rule permits them to deliver a full range of OTP services (e.g., medication dispensing, testing, medication management, and counseling) through the use of permanent structures or motorized vehicles deployed to underserved or hard-to-reach areas. They expand geographic reach of OTPs, particularly in rural areas. Medication Units and Mobile Units must operate under the oversight and license of a certified OTP, in adherence with federal regulations and State rules. Medication Units and Mobile Units have the potential to

significantly expand access to life saving medication for opioid use disorder and support long-term recovery for people with opioid use disorder.

North Carolina currently has one OTP Medication Unit serving 89 of the total 224 patients enrolled in the OTP and its Medication Unit. The existing Medication Unit was opened as a pilot project in 2021, with start-up costs funded by the OTP. North Carolina does not currently have any OTP Mobile Units operating at this time, but there are several in process. To date, the SOTA has granted preliminary approval for five Mobile Units and two Medication Units. Three additional OTPs have expressed interest and are pursuing funding for Mobile Units. One Mobile Unit is pending licensure and is expected to be deployed within the next 60 days.

In the past several years, NC has seen an increase in the number of individuals enrolled in OTPs, from 18,602 in 2019 to 23,849 as of March 7, 2025, a 25% increase (Figure 1). These OTPs have served over 60,000 unique patients since January 2019.

Figure 1: Number of individuals enrolled in North Carolina OTPs between January 2019 and March 2025



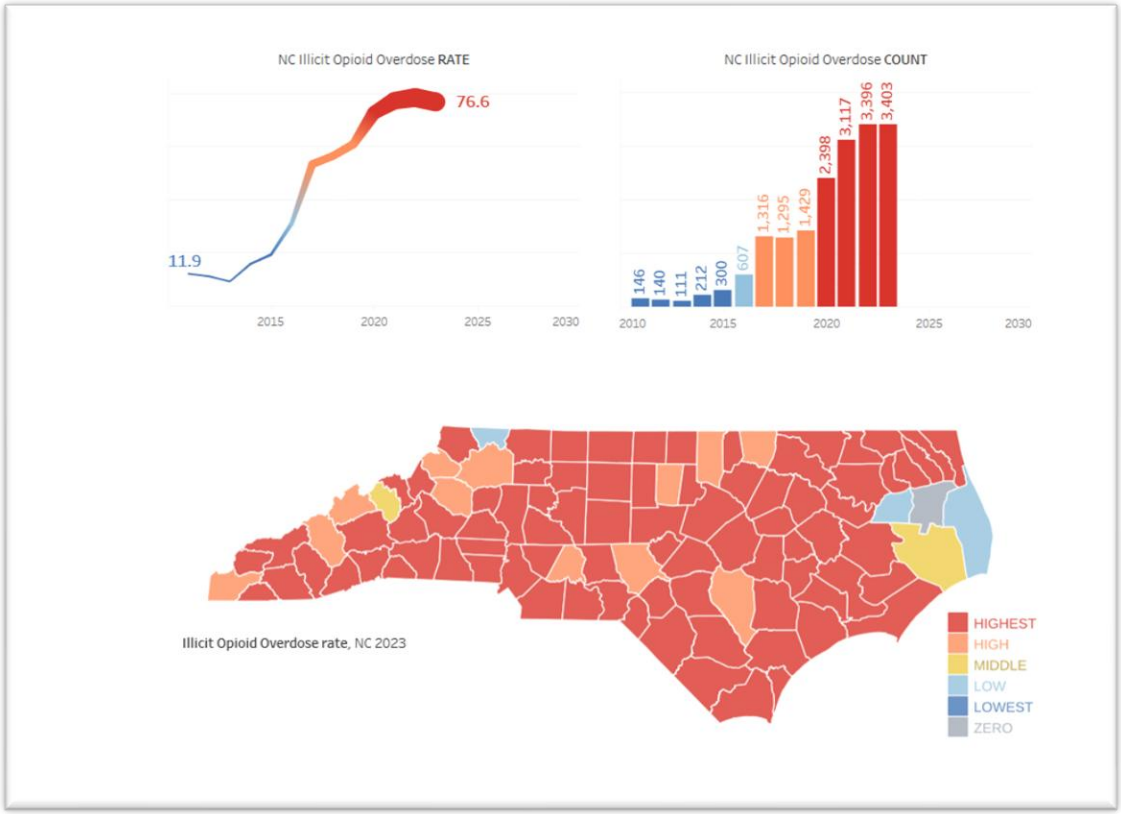
Source: NCDHHS; Lighthouse Central Registry

Approximately 39% of all currently enrolled patients have NC Medicaid. Approximately 21% are funded through State block grant funds with services being authorized by the Local Management Entities-Managed Care Organizations (LME-MCOs).

The numbers of individuals seeking treatment from one of the 90 Opioid treatment Programs has increased every year since the service first became available in North Carolina in 1996, with sharp increases in treatment enrollment every year since 2018. According to the National Survey of Drug Use and Health (NSDUH) for 2023, among the 5.7 million people nationwide with an opioid use disorder, only 18% received medication assisted treatment. Significant barriers to treatment engagement include stigma (or being worried about what people would think or say if they got treatment), cost of treatment, not having enough time for treatment, and limited access, particularly in areas where services are limited or there are barriers such as transportation. Based on trend data, the need for treatment is expected to increase, as is the need for more flexible and available options for delivery of treatment services.

Figure 2 below reflects the rate of illicit opioid related overdoses in North Carolina in 2023. As used here, illicit means a substance that is is either illegal or illegally obtained.

Figure 2: Rate, Count, and Distribution of Illicit Opioid Overdoses in North Carolina



Source: NCDHHS Interactive Overdose Data https://www.dph.ncdhhs.gove/programs/chronic-disease-and-injury/injury-and-violence-prevention-branch/north-carolina-overdose-epidemis-data#data-dashboard

Regulatory Baseline

In this analysis, the impact of the proposed rule is measured against a baseline that includes 10A NCAC 27G, Section .3600; 42 C.F.R., Part 8. Subchapter 1 (Control and Enforcement) of the Controlled Substances Act (CSA), and Federal Drug Enforcement Administration (DEA) regulations 21 C.F.R., Parts 1300 to end, including statutory provisions mandating certain substantive requirements for the rules. This is proposed as a new standalone rule specific to Medication Units and Mobile Unit components of Opioid Treatment Program Facilities. As a result, the following components are part of the regulatory baseline for purposes of this analysis:

- Opioid Treatment Program (OTP) services are governed by 10A NCAC 27G Section .3600. While OTPs must adhere to all applicable rules within the Administrative Code, the rules specific to the delivery of OTP services are found in 10A NCAC 27G .3601-3604.
- Part 8 of Title 42 of the Code of Federal Regulations includes regulations that guide Opioid Treatment Programs (OTPs).
- OTPs are regulated by the Drug Enforcement Administration (DEA), in accordance with Subchapter I (Control and Enforcement) of the Controlled Substances Act (CSA) and DEA regulations 21 C.F.R., Parts 1300 to End.
- G.S. § 122C-35 required the Commission to establish and implement emergency, temporary, and permanent rules for the governance of Opioid Treatment Program Medication Units and Mobile Units. This statute also laid out specific requirements related to licensure of OTP Facilities and Medication Units and Mobile Units, including the amount of the annual licensing fee.

Except where otherwise noted, this analysis is limited to differences from the aforementioned regulatory baseline.

Impact Analysis

This analysis will focus primarily on the following components of the Rule: (1) geographic radius; (2) staffing requirements; and (3) operations and service delivery.

(1) Geographic Radius

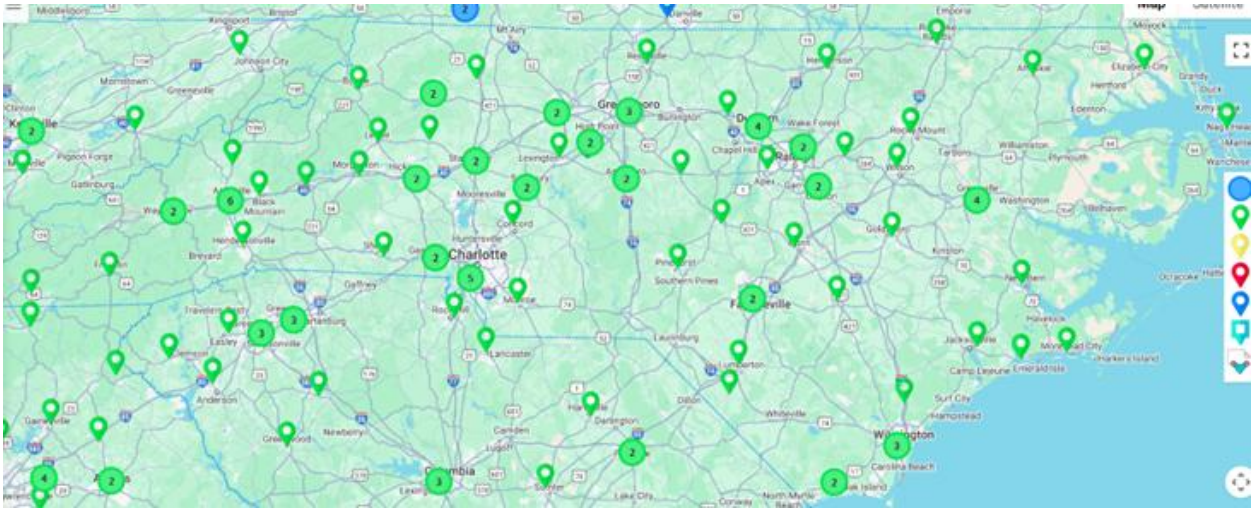
G.S. § 122C-3 defines "Opioid Treatment Program Medication Unit" and "Opioid Treatment Program Mobile Unit" such that they must operate at a "geographically separate location from the opioid treatment program facility." The Rule requires that these units operate withing a radius of 75 miles from the OTP facility.

Geographic limits are proposed to ensure that patients can reasonably return to the OTP Facility to receive any services not offered at the associated Medication Unit and/or Mobile unit in the event that the Medication Unit and/or Mobile Unit become inoperable. This radius also ensures compliance with Rule 10A NCAC 27G .3604(j) which requires that all licensed

outpatient opioid addiction treatment facilities which dispense Methadone, Levo-Alpha-Acetyl-Methadol (LAAM) or any other pharmacological agent approved by the Food and Drug Administration for the treatment of opioid addiction to participate in a computerized Central Registry or ensure that clients are not dually enrolled by means of direct contact or a list exchange with all opioid treatment programs within at least a 75-mile radius of the admitting program.

As of March 2025, there are 90 OTPs operating in NC, and no geographic area within the State is located more than 75 miles away from an OTP Facility (Figure 3).

Figure 3: Distribution of OTPs across NC as of April 2025



Source: https://thecentralregistry.com/map/

Given the current distribution of OTP Facilities across the state, introducing a maximum geographic limit of 75 miles for Medication Units and Mobile Units should not result in any additional costs to providers or individuals using the services. There could be an incremental benefit in the form of clarity to the regulated community from having the geographic limit in the proposed rule being consistent with Rule 10A NCAC 27G .3604(j). This improved clarity could have a marginal impact on providers' compliance with this requirement. Limiting the distance between brick-and-mortar OTP facilities and their associated Medication Units and Mobile Units should also benefit patients by helping to ensure accessibility to this critical treatment. The bulk of the benefit to patients is more appropriately attributed to the statute.

(2) Staffing requirements

Clinical/Counseling Staff:

G.S. 122C-35 requires that the Commission's rules include staffing ratios, but the statute does not specify what those staffing ratios should be. Specifically, the statute requires the rules to address:

- "requisite clinical staff and staffing ratios to meet immediate client needs at each opioid treatment program medication unit or opioid treatment program mobile unit, including client needs for nursing, counseling, and medical care"; and

- "number of clients allowed per opioid treatment program medication unit and opioid treatment program mobile unit, based on staffing ratios."

Rule 10A NCAC 27G .3605(e) proposes requiring a counselor to patient ratio of 1:50 for OTP Medication Units and OTP Mobile Units. A staffing ratio of 1:50 was chosen for consistency with the staffing ratio in existing Rule 10A NCAC 27G .3603(a), which requires a minimum of one certified drug abuse counselor or certified substance abuse counselor to each 50 clients. Under proposed Rule .3605, staffing must include at least one full-time:

- Licensed Clinical Addictions Specialist (LCAS) or
- Licensed Clinical Addictions Specialist – Associate (LCAS-A)

For each additional 50 patients, staffing must include at least one:

- Certified Alcohol and Drug Counselor (CADC)
- Certified Alcohol and Drug Counselor - Intern (CADC-I)
- Licensed Clinical Social Worker (LCSW)
- Licensed Clinical Social Worker – Associate (LCSW-A)
- Licensed Clinical Mental Health Counselor (LMCMC)
- Licensed Clinical Mental Health Counselor – Associate (LCMHC-A)
- Licensed Marriage and Family Therapist (LMFT)
- Licensed Marriage and Family Therapist – Associate (LMFT-A)
- Licensed Psychological Associate (LPA)
- Licensed Psychologist (LP)

The expanded licensure options for counselors permits, but does not require, an OTP to employ staff with these various clinical licenses. Costs related to salaries for staff holding each of the various permitted licenses may vary according to education, years of experience, geographic area, and other factors, and cannot be determined.

The regulatory baseline in 10A NCAC 27G .3603(a) does not include a minimum of one LCAS or LCAS-A but does require a minimum of one certified drug abuse counselor or certified substance abuse counselor per each 50 clients. While a higher level of education may be one factor in determining salary, other variables such as years of experience, geographic area, and other factors may influence salary costs. According to Salary.com, the average salary range for a Certified Alcohol and Drug Counselor (CADC) in North Carolina is estimated from $38,300 - $48,984/year, and the average salary range for an LCAS is between $46,551 - $61,902/year. Based on these factors, the requirement of one LCAS is likely to result in additional costs to the provider of between approximately $0 to $13,000 per year in salary costs for having to hire an employee with a higher level of education. Actual costs would depend primarily on the individual's years of experience, geographic area, and budgetary

constraints. In practice, many providers are already compliant with this requirement and will not need to expend any additional funds.

- Estimated Cost Compared to Regulatory Baseline: $0 to $13,000 in salary costs per year per provider
- Benefits Compared to Regulatory Baseline: Incremental improvement to rule clarity, consistency with existing rules, and compliance with the proposed rule which will help ensure continued patient accessibility to critical services.

Minimum Hours for Medical Director:

Each OTP Facility is required to have a Medical Director who is a physician licensed to practice medicine in the State and who meets the standards and requirements of 42 CFR 8.2 and 42 CFR 8.12(b). The Medical Director of the Facility will serve as the Medical Director for the Facility's associated Medication Unit or Mobile Unit. The Medical Director shall be physically present at the OTP a minimum of four hours per month to assure regulatory compliance and carry out those duties specifically assigned to the Medical Director by regulation. This is a minimum requirement, based on surveys of OTPs indicating that the majority have Medical Directors who are present at the OTP for at least 4 hours per month. There is no maximum limit to the number of hours per month that the Medical Director must be present on site. Salaries of Medical Directors vary depending on factors such as specialty training, board certification, years of experience, geographic area, and other factors, and hourly rates are for OTP Medical Directors are not available.

- Cost Compared to Regulatory Baseline: None
- Benefits Compared to Regulatory Baseline: None other than improvement to rule clarity, consistency with existing practice, and compliance with the proposed rule which will help ensure continued oversight of critical services.

(3) Operations and Service Delivery

G.S. 122C-35 requires that the Commission's rules address OTP Medication and Mobile units' policies and procedures for safe patient care. Specifically, the OTP's policies and procedures must include a "clinical and individualized assessment of individuals to receive services at an opioid treatment program medication unit or opioid treatment program mobile unit that consider medical and clinical appropriateness and accessibility to individuals served." Further, the statute contemplates the need for "the required counseling" to be provided at the mobile and medication units. The statute, while relatively specific in this area, does not prescribe the criteria that an OTP unit must meet to satisfy this "required counseling" condition.

Rule 10A NA 27G .3605(g) addresses the assessment requirements generally:

- (g)(4) "The OTP shall establish and implement policies and procedures for a clinical and individualized assessment of patients to receive services at an OTP Medication

Unit or OTP Mobile Unit that considers medical and clinical appropriateness and accessibility to patients served."

The proposed rule addresses the counseling requirements with some additional specificity:

- (g)(5) "The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive a minimum of two counseling sessions per month during the first year of continuous treatment and a minimum of one counseling session per month after the first year and in all subsequent years of continuous treatment. This frequency of counseling sessions is consistent with existing requirements for OTPs as set forth in Rule 10A NCAC 27G .3604(f) which states, "In addition, during the first year of continuous treatment a patient must attend a minimum of two counseling sessions per month. After the first year and in all subsequent years of continuous treatment a patient must attend a minimum of one counseling session per month."

    - Cost Compared to Regulatory Baseline: None
    - Benefits Compared to Regulatory Baseline: None other than consistency with existing requirements

- (g)(6) "Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of five days per week to offer and provide counseling in accordance with the patient's treatment plan or person-centered plan." The regulatory baseline in 10A NCAC 27G .3603(d) does not specify a minimum number of days per week that each facility must have counseling available. Federal regulation 42 C.F.R., 8.12(f)(1) requires that adequate medical, counseling, vocational, educational, and other services must be fully and reasonably available to patients. In practice, all OTPs currently have counseling staff available either in person or via telehealth at least five days per week at their facility. Including this provision in the proposed rule is not expected to change this existing clinical practice. As such, no additional costs or benefits are expected.

    - Cost Compared to Regulatory Baseline: None
    - Benefits Compared to Regulatory Baseline: None other than consistency with existing practices.

- (g)(7) "The OTP shall establish and implement a policy and procedures to determine the appropriateness of telehealth services for a patient that takes into consideration the patient's choice along with the patient's behavior, physical, and cognitive abilities. The patient's verbal or written consent shall be documented when telehealth services are provided." Telehealth is permitted in Federal regulation 42 C.F.R., 8.12 and may mitigate barriers to engagement in care, such as travel time and cost of travel, when the necessary or desired provider is not physically present at the Medication Unit or Mobile Unit. This rule permits, but does not mandate the use of telehealth. The regulatory baseline in 10A NCAC 27G .3602(8) does not include a telehealth option. The telehealth option herein permits, but does not require, the use of telehealth. If a provider chooses to use telehealth, the cost of adding telehealth via a secure telehealth

platform is estimated at between $20-$40/month per user/provider. Studies have shoen that telehealth results in net costs savings to providers and patients by preventing more costly care, reducing no-show rates, increasing accessibility to care, decreasing travel costs, and increasing productivity for both providers and patients by reducing health care-related travel.[1]

- Estimated Cost Compared to Regulatory Baseline: $20-$40/provider/month, although participation is voluntary
- Benefits Compared to Regulatory Baseline: Unable to calculate, but net benefits are likely for patients and providers if they choose to use the telehealth option.

- (g)(8) "The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive medical interventions, including naloxone, when medically necessary and in compliance with the patient's treatment plan, person-centered plan, standing orders, or emergency interventions protocols." Per Federal Regulation 42 C.F.R., 8.2, OTPs must provide comprehensive treatment which includes medication for opioid use disorder provided with an individualized range of harm reduction, medical, behavioral health, and recovery support services. As defined in 42 C.F.R., 8.2, harm reduction services include distribution of opioid overdose reversal medications. 10A NCAC 27G .3605(g)(8) represents no difference from regulatory baseline.

  - Cost Compared to Regulatory Baseline: None
  - Benefits Compared to Regulatory Baseline: None other than consistency with existing regulations.

Assumptions and Projections

North Carolina currently has 93 OTPs, which is projected to increase to 100 by the end of the 2025 calendar year. At least one mobile unit is projected by the end of the 2025 calendar year.

Based on lessons learned from implementation of Medication Units and Mobile Units in other states, it is anticipated that the Mobile Units and Medication Units will reduce barriers to participation and engagement in treatment, will reduce distances traveled to receive services, and will result in increased retention in treatment, increased patient satisfaction, and increased patient stability.

Both the Medicaid and State funded benefit plan rates are weekly bundled rates that set forth certain staffing requirements for the program and which bundle a variety of activities including managing a medical plan of care and medical monitoring; individualized recovery focused person-centered plan; a minimum of two counseling sessions per month during the first year of treatment and one counseling session per month thereafter; nursing services related to administering medication and preparation, monitoring, and distribution of take home medications; cost of the medication; presumptive drug screens and definitive drug tests;

[1] Taskforce on Telehealth Policy Findings and Recommendations – Telehealth Effect on Total Cost of Care - NCQA

pregnancy tests; tuberculosis tests; psychoeducation consisting of HIV and AIDS education and other health education services; and service coordination activities consisting of coordination with care management entities and coordination of on- and off-site treatment and supports. There is no cost differential based on the location of service.

Per Federal regulations and State rule, each of the Medication Units and Mobile Units will be an extension of a brick-and-mortar home OTP Facility and may travel or be located within a 75-mile radius of the home OTP Facility. While they may serve both rural and urban area, they are most likely to be deployed in more rural areas where treatment access is more lacking or be deployed in rural and urban settings to deliver services, and to people in residential or other short- or long-term care or treatment facilities where medication for opioid use disorder is not currently available.

In a study prepared by Mathematica for the Office of Behavioral Health, Disability, and Aging Policy, Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, January 8, 2025, vehicle costs range from $300,000 to nearly $500,000, depending on the configuration of the unit and whether the unit came from a company that guarantees the vehicle's design will comply with DEA regulations.[2]

Stationary Medication Units must comply with DEA regulations for general security, storage (safes, steel cabinets, or vaults), alarm, surveillance, and accessibility requirements set forth in 21 C.F.R., 1301, and must comply with all state and local occupancy ordinances. As such, there is not a substantial difference in the facility costs between opening a new OTP facility and opening a Medication Unit as an extension of an existing facility. Since a Medication Unit is certified and accredited as part of the home facility, with the potential for shared staff, there may be reduced costs for opening a Medication Unit as compared to opening an independent OTP facility.

Adding a Medication Unit or Mobile unit component to an existing OTP Facility is entirely voluntary.

Affected Parties

The regulated community:

- The regulated community includes all Federally Certified and State Licensed Opioid Treatment Programs in North Carolina. NC Currently has 90 OTPs located throughout the state. A map of all the OTPs in NC can be found via the Central Registry here: https://thecentralregistry.com/map/ and as noted on the map above.
- OTPs are currently regulated by the NC Division of Health Service Regulation under state rule 10A NCAC 27G .3600. For those OTPs who choose to add a Medication Unit or Mobile Unit component to their OTP, the Department shall charge an Opioid treatment Program Facility a nonrefundable annual license fee plus a nonrefundable annual per-unit fee of two hundred sixty-five dollars ($265.00) for each OTP Medication Unit or OTP Mobile Unit, as set forth in G.S. 122C-35(f). The cost to the OTP for purchase or lease of the Medication Unit building, purchase or lease of the

[2] Implementation of Mobile Medication Units: Findings from a Qualitative Study

Mobile Unit, and any costs associated with upfitting the associated Unit to be in compliance with regulations would vary depending on the services that the OTP chooses to offer at the Medication Unit or Mobile Unit as well as the configuration of each individual unit.

Federal government entities:

- Drug Enforcement Agency (DEA) Diversion Control Division performs on-site inspections before and after registration approval. Costs may include mileage to travel to the associated unit and additional time needed for the on-site inspection.
- SAMHSA's Center for Substance Abuse Treatment (CSAT) is responsible for certifying that an OTP conforms with federal regulations governing treatment for substance use disorders. Costs may include additional time needed for processing the applications for initial certification and renewal.

National Accreditation Bodies:

- Accreditation bodies may conduct virtual or on-site reviews prior to and upon renewal of accreditation. Costs to the provider may include mileage to travel to an associated Medication Unit. There would be no costs associated with travel to a Mobile Unit, as the mobile unit would be brought to the facility during the course of normal operations. Accreditation reviews are typically conducted over a period of several days, and no additional time for review of the associated units is anticipated.

State government entities:

- DMH/DD/SUS –
    - State Opioid Treatment Authority (SOTA) conducts inspections annually or in response to a complaint or concern. As the Medication Units and Mobile Units are components of the OTP Facility, records of patients served through the Medication Units or Mobile Units will be reviewed during the same site visit. Medication Units and Mobile Units are required to operate within a 75-mile radius of the home OTP Facility; therefore, in-person inspection of any associated units may be conducted as needed during the scheduled site visit. Costs may include mileage to travel to the associated unit and additional time needed for the on-site review.
    - Drug Control Unit performs on-site inspections before registration approval and may perform inspections after registration approval. Costs may include mileage to travel to the associated unit and additional time needed for the on-site review.
- DHSR – Per G.S. § 122C-35, notwithstanding G.S. § 122C-25(a), an opioid treatment facility with no previous violations of State or Federal requirements for opioid treatment programs may be subject to inspection once every other year, excluding any complaint investigation. An Opioid Treatment Program Facility with either an OTP Medication Unit or OTP Mobile Unit may be subject to annual inspections. Medication Units and Mobile Units are required to operate within a 75-mile radius of the home OTP Facility; therefore, in-person inspection of any associated units may be

conducted as needed during the scheduled site visit. Costs may include mileage to travel to the associated unit and additional time needed for the on-site review.

NC Medicaid and State-funded Benefit Plan:

- Both the Medicaid and State-funded benefit plan rates are weekly bundled rates that set forth certain staffing requirements for the program and which bundle a variety of activities, as noted above. There is no cost differential based on the location of service.

Individual, Local Government, and Community Impacts:

- The proposed rule will not result in any additional cost to the patient who receives OTP services at a Medication Unit or Mobile Unit. Individuals needing treatment would only stand to benefit by having more convenient and accessible treatment locations, which could reduce time and cost associated with travel to the provider. There would be no cost or risk to the patients.
- Engaging and retaining people in treatment will have positive effects on the individual and community. Studies have shown that the US economic cost of opioid use disorder ($471 billion) and fatal opioid overdose ($550 billion) totals over $1.3 trillion annually.
- Opioid use disorder is rising, but most people with OUD did not receive evidence-based medication treatment. Only about 20 to 25% of adults needing OUD treatment received medications in recent years, with even lower rates among women, younger, adults, and some minority groups.[3,4]
- Research consistently shows that that medications for OUD, such as methadone and buprenorphine, improve outcomes by reducing relapse, overdose risk, and healthcare costs, especially when treatment is sustained for longer periods (over 15 months).[5] Adherence to these medications is crucial; patients who stick to their medication regimens have significantly lower relapse rates, fewer emergency and inpatient visits, and lower overall healthcare costs compared to non-adherent patients.[6] Barriers to adherence include inconvenient appointments and transportation issues, which mobile and medication units aim to address.[7]
- Effective treatment and retention not only benefit individuals but also reduce the enormous economic burden of OUD which costs the U.S. nearly $1.5 trillion in 2020 alone.[8] The US Centers for Disease Control (CDC) estimates the costs per person for components of opioid use disorder, including healthcare - $14,705, criminal justice -

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[3] Dowell D, Brown S, Gyawali S, et al. Treatment for Opioid Use Disorder: Population Estimates – United States, 2022. *MMWR Morb Mortal Wkly* Rep 2024; 73:567-574.

[4] Jones CM, HanB, Baldwin GT, Einstein EB, Compton WM, Use of Medication for Opioid Use Disorder Among Adults with Past-Year Opioid Use Disorder in the US, 2021. *JAMA Netw Open*. 2023;6(8):e2327477.

[5] Medications for Opioid Use Disorder Improve Patient Outcomes | *The Pew Charitable Trusts*

[6] Kinsky S, Houck PR, Mayes K, Loveland D, Daley D, Schuster JM. A comparison of adherence , outcomes, and costs among opioid use disorder Medicaid patients treated with buprenorphine and methadone: A view from the payer perspective. *J Subst Abuse Treat.* 2019 Sept1045-21.

[7] Smith C, Keever A, Bowden T, Olson K, Rodin N, McDonell M, Roll J, Smoody G, LeBrun J, Miguel A, McPherson S. Patient Feedback on a Mobile Medication Adherence App for Buprenorphine and Naloxone: Closed and Open-Ended Survey on Feasibility and Acceptability, *JMIR Form* Res 2023;7:e40437

[8] https://www.jec.senate.gov/public/index.cfm/democrats/2022/9/the-economic-toll-of-the-opioid-crisis-reached-nearly-1-5-trillion-in-2020

$6,961, lost productivity - $14,707, and reduced quality of life - $83,186.[9] When both healthcare costs and criminal justice costs were included in cost modeling, all forms of medication assisted treatment were associated with cost savings compared with no treatment, yielding savings of $25,000 to $105,000 in lifetime costs per person, with the largest cost savings associated with methadone plus behavioral interventions such as contingency management.[10]

- Local government entities do not have a role in regulating or operating OTPs beyond enforcement of general zoning laws and building and fire codes. Local economies may benefit from any regulation that improves access to opioid treatment programs. If there are fewer overdose incidents and hospital visits, that could lower healthcare and emergency response costs. Drug-related crimes may also be reduced, which would enhance the safety of the community.

Summary

Allowing OTPs with brick-and-mortar locations to operate mobile units within 75 miles is expected to deliver net benefits to patients, local governments (indirectly) and the broader community. Importantly, the rule does not mandate providers to operate medication or mobile units. Participation is entirely voluntary, so any associated costs will be incurred at the provider's discretion.

While it is uncertain whether providers will realize a net financial benefit – given the significant upfront investment in vehicles and ongoing costs for staffing and maintenance – mobile units have demonstrated clear public health advantages. If deployed, these units can greatly expand access to opioid use disorder treatment for individuals facing transportation barriers, those in rural or underserved areas, and people unable to reliably reach fixed-site clinics. Research shows that mobile OTPs improve treatment retention and outcomes, reduce overdose risk, and deliver evidence-based care to marginalized populations. Over time, these improvements can translate to reduced healthcare and societal costs by preventing overdoses and supporting sustained recovery.

If mobile or medication units are deployed, NC DHHS will collect additional revenue through a modest annual license fee of $265 per unit. The Department will also incur opportunity costs associated with reviewing license applications and conducting inspections at mobile and medication unit locations.

The future number of medication units and mobile units in North Carolina remains unknown. However, based on interest expressed to the State Opioid treatment Authority (SOTA), there appears to be interest from several OTPs. To date, the SOTA has granted preliminary approval for five Mobile Units and two Medication Units, and three additional OTPs have stated interest and are working on obtaining funding for Mobile Units. One Mobile Unit is pending

[9] Luo F, Li M, Florence C. State-Level Economic Costs of Opioid Use Disorder and Fatal Opioid Overdoses – United Stated, 2017. *MMWR Morb Mortal Wkly* Rep 2021;70:541-546.
[10] Fairley M, Humphreys K, Joyce VR, et al. Cost-Effectiveness of Treatments for Opioid Use Disorder, *JAMA Psychiatry*. 2021;78(7):767-777.

licensure and is expected to be deployed within the next 60 days. However, the majority of costs and benefits associated with their operation will be attributable to underlying statute rather than the proposed rule itself. The rule's primary contribution is to establish a clear regulatory framework, ensuring safe, standardized operation and licensing of Medication Units and Mobile Units, and setting minimum standards for staffing, Medical Director oversight, and patient care policies and procedures. This clarity will help ensure that OTP Medication Units and Mobile Units are implemented safely and effectively, maximizing their positive impact.

ATTACHMENT

Proposed Adoption of Rule

10A NCAC 27G .3605, *Medication Units and Mobile Units*

Rule 10A NCAC 27G .3605 is proposed for adoption via permanent procedures as follows.

10A NCAC 27G .3605 Medication Units and Mobile Units

(a) Definitions

(1) "Opioid Treatment Program" (hereinafter, OTP) means the same as defined in G.S. §122C-3(25a).

(2) "Opioid Treatment Program Facility" (hereinafter OTP Facility) means the primary location on the facility license.

(3) "Opioid Treatment Program Medication Unit" (hereinafter OTP Medication Unit) means the same as defined in G.S. § 122C-3(25b).

(4) "Opioid Treatment Program Mobile Unit" (hereinafter OTP Mobile Unit) means the same as defined in G.S.§ 122C-3(25c).

(b) The OTP Facility shall provide any medical, counseling, vocational, educational, and other assessment and treatment services not provided by the OTP Medication Unit or OTP Mobile Unit.

(c) The OTP shall determine the type of services to be provided at the OTP Medication Units and OTP Mobile Units. The OTP shall clearly specify which services are offered at the OTP Medication Units and OTP Mobile Units. Any services not offered at the OTP Medication Unit or Mobile Unit shall be provided at the OTP facility.

(d) Location and Service Capacity.

(1) The OTP shall ensure that each OTP Medication Unit and OTP Mobile Unit complies with all applicable State and Federal laws and regulations, including without limitation, Substance Abuse and Mental Health Services Administration and Federal Drug Enforcement Agency regulations governing their operation.

(2) An OTP with geographically separate OTP Medication Units and OTP Mobile Units shall maintain and provide the location of each unit associated with the OTP.

(3) The OTP Medication Units and Mobile Units shall operate within a radius of 75 miles from the Opioid Treatment Program facility.

(4) The OTP shall maintain and provide schedules for the days and hours of operation to meet patient needs.

(5) The OTP shall establish and implement an operating protocol identifying the number of patients allowed per OTP Medication Unit and OTP Mobile Unit based on staffing ratios.

(6) The OTP shall establish and implement an operating protocol which includes predetermined location(s), hours of operations, and a daily departure guide and business record of each OTP Mobile Unit's location.

(e) Staffing Requirements. The OTP shall maintain standard operating and emergency staffing to ensure service delivery at the OTP and any associated OTP Medication Units and OTP Mobile Units. Staffing shall include, but not be limited to the following:

(1) The OTP shall have a 1.0 FTE Licensed Clinical Addiction Specialist (LCAS), or Licensed Clinical Addiction Specialist-Associate (LCAS-A) per 50 patients. This position can be filled by more than one LCAS or LCAS-A staff member (ratio 1:50); and

(2) The OTP shall have 1.0 FTE LCAS, LCAS-A, Certified Alcohol and Drug Counselor (CADC), Certified Alcohol and Drug Counselor Intern (CADC-I), Licensed Clinical Social Worker (LCSW), Licensed Clinical Social Worker – Associate (LCSW-A), Licensed Clinical Mental Health Counselor (LCMHC), Licensed Clinical Mental Health Counselor – Associate (LCMHC-A), Licensed Marriage and Family Therapist (LMFT), Licensed Marriage and Family Therapist – Associate (LMFT-A), Licensed Psychological Associate (LPA), or Licensed Psychologist (LP) for each additional 50 patients in the program (ratio 1:50); and

(3) The OTP shall have a Medical Director who is a physician licensed to practice medicine in North Carolina and who meets the standards and requirements outlined in 42 CFR § 8.2 and 42 CFR § 8.12(b).

(A) The Medical Director is responsible for ensuring all medical, psychiatric, nursing, pharmacy, toxicology, and other services offered at the OTP and any associated OTP Medication Units and OTP Mobile Units are conducted in compliance with State and Federal laws and regulations, consistent with appropriate standards of care; and

(B) The Medical Director shall be physically present at the OTP a minimum of 4 hours per month to assure regulatory compliance and to carry out those duties assigned to the Medical Director in 42 CFR §8.2 and 42 CFR § 8.12(b)(2).

(C) The Medical Director shall be responsible for supervision of any physician extender(s) and other medical staff.

(f) Each OTP shall develop and implement a policy regarding the maintenance, location, and retention of records for its OTP Medication Units and OTP Mobile Units, in accordance with State and Federal laws and regulations.

(g) Operations and Service Delivery

(1) Each OTP Medication Unit and OTP Mobile Unit shall be deemed part of the OTP license and shall be subject to inspections the Department deems necessary to validate compliance with all applicable rules, and State and Federal laws and regulations.

(2) The OTP shall ensure that its OTP Medication Units and OTP Mobile Units adhere to all State and federal program requirements for Opioid Treatment Programs.

(3) Each OTP Medication Unit and OTP Mobile Unit shall establish and implement a written policy and procedure for operations that meets the needs of its patients.

(4) The OTP shall establish and implement policies and procedures for a clinical and individualized assessment of patients to receive services at an OTP Medication Unit or OTP Mobile Unit that considers medical and clinical appropriateness and accessibility to patients served.

(5) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive a minimum of two counseling sessions per month during the first year of continuous treatment and a minimum of one counseling session per month after the first year and in all subsequent years of continuous treatment.

(6) Counseling staff shall be available, either in person and on-site or by telehealth, a minimum of five days per week to offer and provide counseling in accordance with the patient's treatment plan or person-centered plan.

(7) The OTP shall establish and implement a policy and procedure to determine the appropriateness of telehealth services for a patient that takes into consideration the patient's choice along with the patient's behavior, physical, and cognitive abilities. The patient's verbal or written consent shall be documented when telehealth services are provided.

(8) The OTP shall ensure that patients receiving services at an OTP Medication Unit or OTP Mobile Unit receive medical interventions, including naloxone, when medically necessary and in compliance with the patient's treatment plan, person-centered plan, standing orders, or emergency intervention protocols.

(9) An OTP and its associated OTP Medication Units and OTP Mobile Units shall ensure that all dosing of medication to patients on the site of the OTP and any associated OTP Medication Units and OTP Mobile Units is directly observed by a Physician, Physician Assistant, Nurse Practitioner, Pharmacist, Registered Nurse, or Licensed Practical Nurse, in accordance with applicable State and Federal Law and the OTP's Diversion Control Plan.

History Note: *Authority G.S. 122C-35; 42 C.F.R. § 8.12;*
Emergency Eff. September 23, 2024;
Temporary Eff. January 2, 2025;
Eff. _____.