



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

ROY COOPER • Governor

KODY H. KINSLEY • Secretary

MARK PAYNE • Director, Division of Health Service Regulation

MEMORANDUM

TO: Opioid Treatment Programs

FROM: Robin Sulfridge, Chief, Mental Health Licensure and Certification Section

DATE: October 11, 2023

RE: Request for Temporary Waiver of 10A NCAC 27G .3604 (f)(1)(A)-(G), (f)(2)(A)-(C) and (f)(3)(A), 10A NCAC 27G .3601 SCOPE (a), 10A NCAC 27G .3602 DEFINITIONS (8), and 10A NCAC 27G .3603 STAFFING (a), (b)

The Substance Abuse and Mental Health Services Administration (SAMHSA) has granted a temporary exemption from the unsupervised take-home medication requirements of 42 C.F.R. § 8.12(i) that are necessary to:

- (1) dispense up to 7 unsupervised take-home doses of methadone for a patient in treatment 0-14 days;
- (2) up to 14 unsupervised take-home doses of methadone may be provided to the patient in treatment days 15-30; and
- (3) up to 28 unsupervised take-home doses of methadone may be provided to the patient from 31 days in treatment, if the Opioid Treatment Program (OTP) believes the patient can safely handle the amount of take-home medication, with applicable conditions.

(Herein referred to as "SAMHSA's temporary exemption"). See, [Methadone TakeHome Flexibilities Extension Guidance | SAMHSA](#)

Pursuant to Rule 10A NCAC 27G .0806, a waiver request was made by the Division of Mental Health, Developmental Disabilities and Substance Use Services (DMH), Director on September 26, 2023. The request was to support modifying the current waiver extending the methadone take-home flexibilities to include the following components of 10A NCAC 27G .3604(f)(2)(A)-(C), which addresses criteria for reducing, losing and reinstatement of take-home eligibility. Federal regulation 42 C.F.R. §8.12 and SAMHSA's Federal Guidelines do not address criteria for reducing or losing take-home eligibility and allow for the clinical judgement of the OTP practitioner. Moving forward, including 10A NCAC 27G .3604(f)(2)(A)-(C) in the temporary waiver is essential to OTPs' ability to implement take-home flexibilities according to SAMHSA's Guidance and in accordance with the approved waivers for (f)(1) and (f)(3) referenced above.

In a separate waiver request on September 21, 2023, the DMH concurred with the letter dated November 1, 2017, where the Centers for Medicare and Medicaid Services issued SMD #17-003

MENTAL HEALTH LICENSURE & CERTIFICATION SECTION

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detailing strategies to address the opioid epidemic. The announcement reflected an intent, pursuant to Section 1115(a) demonstrations, to improve access to and quality treatment of Medicaid beneficiaries in an effort to combat the ongoing opioid crisis.

The requested waivers are contingent upon the OTP's attestation of compliance with the alternative language provided in its stead. The alternative language is consistent with standards implemented by the American Society of Addictive Medicine as well as the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Furthermore, the alternative language imposes safeguards intended to ensure that the health, safety, and welfare of the consumers served during the duration of these waivers will not be threatened.

Pursuant to North Carolina General Statute § 122C-23(f), the Department of Health and Human Services' Division of Health Service Regulation (DHSR) may, based on a written application and for good cause, waive any of the rules implementing Article 2 of Chapter 122C so long as those rules do not affect the health, safety, or welfare of individuals served by the facility. Upon receipt and approval of an OTP's request for a waiver (using the request form attached to this memorandum), based on SAMHSA's temporary exemption and the DMH Director's request, DHSR will temporarily waive 10A NCAC 27G .3604 (f)(1)(A)-(G), (f)(2)(A)-(C) and (f)(3)(A) and 10A NCAC 27G .3601 SCOPE (a), 10A NCAC 27G .3602 DEFINITIONS (8), and 10A NCAC 27G .3603 STAFFING (a), (b) subject to the OTP representing and agreeing to the parameters set forth in the attached document. DHSR is exercising this authority to waive rules in order to align with the SAMHSA temporary exemptions and State strategies to address the opioid epidemic and improve access and quality of care.

OTPs may request a temporary waiver of **10A NCAC 27G .3604 (f)(1)(A)-(G), (f)(2)(A)-(C) and (f)(3)(A)** and **10A NCAC 27G .3601 SCOPE (a), 10A NCAC 27G .3602 DEFINITIONS (8), and 10A NCAC 27G .3603 STAFFING (a), (b)** by **competing and signing the two attached documents** and returning them to DHSR's Mental Health Licensure and Certification Section, Pam Pridgen, Administrative Supervisor, via email (pam.pridgen@dhhs.nc.gov).

Attachment

cc: Julie Cronin
Bethany Burgon
Emery Milliken
Mark Payne