



JAN 24 2008

Dear Colleague:

The purpose of this letter is to restate the Substance Abuse and Mental Health Services Administration's (SAMHSA) policy for unsupervised medication take-home doses when the opioid treatment program (OTP) is closed for business, including Sundays and Federal and State holidays. Federal policy, as set forth below in SAMHSA regulations, guidelines, and previous "Dear Colleague" letters, has not changed since the U.S. Food and Drug Administration (FDA) rules were promulgated in 1989, with respect to the requirement that an assessment, and documentation of the assessment by the program's medical director, is necessary for each take-home dose provided to a patient.

The July 22, 1999 Federal Register Notice titled "Narcotic Drugs in Maintenance and Detoxification Treatment of Narcotic Dependence; Repeal of Current Regulations and Proposal to Adopt New Regulations; Proposed Rule," stated that:

the medical director shall be responsible for determining whether a patient can responsibly handle opioid treatment drugs for unsupervised use. In addition, **all decisions** on take-home medications would be documented in the patient's medical chart. The basis for the medical director's clinical judgment must be, at a minimum, the eight criteria listed currently in 291.505(d)(6)(iv)(B). (emphasis added) [The 8-point criteria listed in §291.505(d)(6)(iv)(B) are identical to the listing in 42 C.F.R. 8.12(i)(2).]

The final SAMHSA regulations at 42 C.F.R. 8.12(i)(2) state that:

Treatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in paragraph (i)(1) of this section, shall be determined by the medical director. In determining which patients may be permitted unsupervised use, the medical director shall consider the following take-home criteria in determining whether a patient is responsible in handling opioid drugs for unsupervised use.

- (i) Absence of recent abuse of drugs (opioid or nonnarcotic), including alcohol;
- (ii) Regularity of clinic attendance;
- (iii) Absence of serious behavioral problems at the clinic;
- (iv) Absence of known recent criminal activity, *e.g.*, drug dealing;
- (v) Stability of the patient's home environment and social relationships;
- (vi) Length of time in comprehensive maintenance treatment;

- (vii) Assurance that take-home medication can be safely stored within the patient’s home; and
- (viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

Additionally, SAMHSA’s Guidelines for the Accreditation of Opioid Treatment Programs (July 19, 2007) provides elaboration on this issue. Under Chapter 2, section V, titled “Unsupervised Approved Use (Take-Home Medication),” it states that:

[i]n determining patient eligibility for **any** take-home medication, including a single take-home dose for a day that the clinic is closed for business, such as Sundays and State and Federal holidays, the program physician considers the eight-point criteria and employs good clinical judgment. (emphasis added)

We recognize that 42 C.F.R. 8.12(i)(1) states that “[a]ny patient in comprehensive maintenance treatment **may** receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays” (emphasis added). Some OTPs may have interpreted this provision to mean that the determination to provide a patient with a single take-home dose need not be made in conjunction with the determination required in 8(i)(2). The single take-home dose provision does not automatically extend to a patient who the medical director has determined to be ineligible for a take-home dose. In addition, 8.12(i)(3) states that “[s]uch determinations and the basis for such determinations consistent with the criteria outlined in paragraph (i)(2) of this section shall be documented in the patient’s medical record.” This section applies to (i)(1) as well as (i)(2), that the 8-point criteria must be considered and documented for patients even for clinic closures.

Even though the 8-point criteria must be considered in the determination to provide unsupervised medication use for all patients, the assessment does allow for a physician to use clinical judgment in determining whether a patient is responsible in handling a take-home dose(s) and whether the rehabilitative benefit the patient would gain from reduced attendance for directly observed dosing outweighs the potential risk of diversion.

OTPs that close for business on a day of the week or for a Federal or State holiday should have an arrangement in place to permit each patient who the medical director has determined not to be an appropriate candidate for take-home medication use to be dosed under supervision. For example, the OTP could have an arrangement with a medical facility (hospital) or another OTP in the community to permit the patient to be medicated under appropriate medical supervision. Or the OTP may decide to open for a limited period of time to dispense to patients not eligible for the take-home supply. We also refer you to our Dear Colleague Letter dated November 7, 2005 (<http://www.dpt.samhsa.gov/pdf/dearColleague/2006-01-Holiday-Closures.pdf>).

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For additional information or questions, please contact Jennifer Fan, Pharm.D., J.D.,  
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Sincerely,

A handwritten signature in black ink, appearing to read "H. Westley Clark". The signature is fluid and cursive, with a large, sweeping flourish at the end.

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM  
Director  
Center for Substance Abuse Treatment