

- (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>).

