



MAY 14 2008

Dear Colleague:

The purpose of this letter is to emphasize that according to 42 C.F.R. 8.12(i)(5), the take-home medication bottles should be properly labeled with the opioid treatment program's (OTP's) name, address, and telephone number. The Substance Abuse and Mental Health Services Administration (SAMHSA) also recommends including the patient's name, the medication name, the physician's name, and the dispensing date. In addition, prescription labels for liquid methadone should include the dose and the directions of use such as "single dose" while prescription labels for Suboxone[®] or Subutex[®] and methadone dispersible tablets should include the strength, quantity dispensed, and the appropriate directions of use such as "Take [#] tablet(s) under the tongue once a day" or "Take [#] tablet(s) once a day," respectively.

Appropriate cautionary statements should also appear on the take-home bottle. According to 21 C.F.R. 290.5, "[t]he label of any drug listed as a 'controlled substance' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: 'Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'"

We believe that the inclusion of the above information on take-home bottle labels will help reduce diversion of methadone and buprenorphine and improve patient safety. The display of the patient's name on the take-home bottle label should help reduce diversion since the label can lead back to the patient if the medication was diverted and the bottle was found. The inclusion of the medication name, dose or strength and quantity, direction of use, physician name, dispensing date, as well as the patient name, will improve patient safety by providing necessary information to the patient so that the patient can accurately identify the contents in the bottle, the direction of use, and the physician who prescribed the medication. This information is also useful in emergency situations where someone has ingested the contents in the bottle.

Enclosed are examples of take-home bottle labels that include the above required and recommended information. SAMHSA acknowledges that states may have specific requirements that may not be addressed by the SAMHSA sample label. The sample labels are for guidance purposes only.

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For additional information or questions, please contact Jennifer Fan, Pharm.D., J.D.,
Public Health Advisor, at (240) 276-1759 or by e-mail at Jennifer.fan@samhsa.hhs.gov.

Sincerely,

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

Enclosure

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Example 1:

X Y Z Recovery Services	1111 State Street Sunshine, Alaska 00000 301.555.5555
[Patient Name]	
Dispense Date: 01/02/2008	
Methadone 60mg	Directions: Single Dose
[Name of OTP Medical Director or Physician]	

CAUTION:
Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Example 2:

X Y Z Recovery Services	1111 State Street Sunshine, Alaska 00000 301.555.5555
[Patient Name]	
Dispense Date: 01/02/2008	
Suboxone 8 mg	QTY: 14 Directions: Take 2 tablets under the tongue once a day
[Name of OTP Medical Director or Physician]	

CAUTION:
Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.