

provider in connection with your planning and/or scheduling an official conference or other group travel (as opposed to performing official travel yourself) are considered property of the Government, and you may only accept the benefits or materials on behalf of the Federal Government (*see* § 301–74.1(d) of this chapter).

■ 3. Revise § 301–53.3 to read as follows:

§ 301–53.3 How may I use promotional materials and frequent traveler benefits?

Promotional materials and frequent traveler benefits may be used as follows:

(a) You may use frequent traveler benefits earned on official travel to obtain travel services for a subsequent official travel assignment(s); however, you may also retain such benefits for your personal use, including upgrading to a higher class of service while on official travel.

(b) If you are offered such benefits as a result of your role as a conference planner or as a planner for other group travel, you may not retain such benefits for your personal use (*see* § 301–53.2 of this chapter). Rather, you may only accept such benefits on behalf of the Federal Government. Such accepted benefits may only be used for official Government business.

PART 301–74—CONFERENCE PLANNING

■ 4. The authority citation for 41 CFR part 301–74 continues to read as follows:

Authority: 5 U.S.C. 5707.

■ 5. Amend § 301–74.1 by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 301–74.1 What policies must we follow in planning a conference?

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(d) Ensure that the conference planner or designee does not retain for personal use any promotional benefits or materials received from a travel service provider as a result of booking the conference (*see* §§ 301–53.2 and 301–53.3 of this chapter); and

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

42 CFR Part 8

RIN 0910–AA52

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Addition of Buprenorphine and Buprenorphine Combination to List of Approved Opioid Treatment Medications

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services.

ACTION: Interim final rule.

SUMMARY: This interim final rule amends the Federal opioid treatment program regulations by adding buprenorphine and buprenorphine combination products to the list of approved opioid treatment medications that may be used in federally certified and registered opioid treatment programs. The Food and Drug Administration (FDA) recently approved Subutex® (buprenorphine) and Suboxone® (buprenorphine in fixed combination with naloxone) for the treatment of opiate dependence. These two products will join methadone and ORLAAM® as medications that may be used in opioid treatment programs for the maintenance and detoxification treatment of opioid dependence. Opioid treatment programs that choose to use these new products in the treatment of opioid dependence will adhere to the same Federal treatment standards established for methadone and ORLAAM®. The Secretary invites public comments on this action.

DATES: This interim final rule is effective May 22, 2003. This interim final rule is also being presented here for public comments. Written comments must be received by the Substance Abuse and Mental Health Services Administration (SAMHSA) on or before July 21, 2003.

ADDRESSES: Comments should be submitted to the Division of Pharmacologic Therapy, Center for Substance Abuse Treatment, Rockwall II, Room 6–18, 5600 Fishers Lane, Rockville, MD, 20857; Attention: DPT Federal Register Representative.

FOR FURTHER INFORMATION CONTACT: Nicholas Reuter, Center for Substance Abuse Treatment (CSAT), Division of Pharmacologic Therapy, SAMHSA, Rockwall II Room 6–18, 5600 Fishers

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SUPPLEMENTARY INFORMATION:

Background

In a rule document published in the *Federal Register* of January 17, 2001 (66 FR 4076, January 17, 2001), the Substance Abuse and Mental Health Services Administration (SAMHSA) issued final regulations for the use of narcotic drugs in maintenance and detoxification treatment of opioid addiction. That final rule established an accreditation-based regulatory system under 42 CFR part 8 (“Certification of Opioid Treatment Programs,” “OTPs”). The regulations also established (under § 8.12) the Secretary’s standards for the use of opioid medications in the treatment of addiction, including standards regarding the quantities of opioid drugs which may be provided for unsupervised use.

Section 8.12(h) sets forth the standards for medication administration, dispensing and use. Under this section, OTPs shall use only those opioid agonist treatment medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for use in the treatment of opioid addiction. The regulation listed methadone and levomethadyl acetate (ORLAAM®) as the opioid agonist treatment medications considered to be approved by the FDA for use in the treatment of opioid addiction.

On October 8, 2002, FDA approved two new opioid treatment medications, buprenorphine and buprenorphine combination for the treatment of opioid addiction. These medications are controlled under schedule III of the Controlled Substances Act (“CSA,” 21 U.S.C. 812). *See* final rule published October 7, 2002 (67 FR 62354). By adding these two medications to the previous list of approved opioid treatment medications, the Secretary allows OTPs to use buprenorphine and buprenorphine combination for the treatment of opioid addiction. OTPs will apply the same treatment standards that were finalized on January 17, 2001, for methadone and ORLAAM®.

Summary of Regulation

The opioid treatment program regulations (42 CFR part 8) establish the procedures by which the Secretary will determine whether a practitioner is qualified under section 303(g) of the CSA (21 U.S.C. 823(g) (1)) to dispense certain therapeutic narcotic drugs in the treatment of individuals suffering from narcotic addiction. These regulations