DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 8

[Docket No. 2012-29417]

RIN-0930-AA14

Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Proposed Modification of Dispensing Restrictions for Buprenorphine and Buprenorphine Combination as Used in Approved Opioid Treatment Medications; Correction

AGENCY: Substance Abuse and Mental Health Services Administration, HHS

ACTION: Final rule; correction.

SUMMARY: The Health and Human Services Department (HHS) is correcting a final rule that appeared in the Federal Register of December 6, 2012. The document modified the dispensing requirements buprenorphine and buprenorphine combination products approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs. In particular, this rule allows opioid treatment programs more flexibility in dispensing take-home supplies of buprenorphine after the assessment and documentation of a patient's responsibility and stability to receive opioid addiction treatment medication. However, an inadvertent removal of paragraphs was made. This correction reinstates the missing paragraphs.

DATES: Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Jinhee Lee, Division of Pharmacologic Therapies, Center for Substance Abuse Treatment, SAMHSA, 1 Choke Cherry Road, Room 7-1028, Rockville, MD 20857, (240) 276-2700, email: Jinhee.Lee@samhsa.hhs.gov.

SUPPLEMENTARY INFORMATION: On December 6, 2012 (77 FR 72752), HHS published a final rule in the Federal Register modifying the dispensing requirements in 42 CFR 8.12 for buprenorphine and buprenorphine combination products approved by FDA for opioid dependence and used in federally certified and registered opioid treatment programs. An inadvertent error was made whereby § 8.12(i)(3)(i) through (vi) was deleted. The original intention was only to revise § 8.12(i)(3) introductory text, however, this was not made clear and thus the entire section following the introductory text was removed. This correction properly modifies the dispensing requirements in 42 CFR 8.12 as published in the Federal Register on December 6, 2012, without removing § 8.12(i)(3)(i) through (vi).

List of Subjects in 42 CFR Part 8

Health professions, Levo-AlphaAcetyl-Methadol (LAAM), Methadone, Reporting and recordkeeping requirements

PART 8—CERTIFICATION OF OPIOID TREATMENT PROGRAMS

1. The authority citation for part 8 continues to read as follows:

Authority: 21 U.S.C. 823; 42 U.S.C. 290bb–2a, 290aa(d), 290dd–2, 300x–23, 300x–27(a), 300y–11.

2. In § 8.12, paragraph (i)(3) is revised to read as follows:

§ 8.12 Federal opioid treatment standards.

* * * * *

(i) * * *

(3) Such 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. If it is determined that a patient is responsible in handling opioid drugs, the dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section apply. The dispensing restrictions set forth in paragraphs (i)(3)(i) through (vi) of this section do not apply to buprenorphine and buprenorphine products listed under paragraph (h)(2)(iii) of this section.

(i) During the first 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision as provided for under the regulations in this subpart.

(ii) In the second 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are two doses per week.

(iii) In the third 90 days of treatment, the take-home supply (beyond that of paragraph (i)(1) of this section) are three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

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Dated: June 4, 2015.

Oliver Potts,

Deputy Executive Secretary,

U.S. Department of Health and Human Services.

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