

EPA APPROVED NEW MEXICO REGULATIONS—Continued

State citation	Title/Subject	State approval/ effective date	EPA Approval date	Comments
20.2.99.3	Statutory Authority	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.4	Duration	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.5	Effective Date	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.6	Objective	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.7	Definitions	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.8	Documents	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.101	Applicability	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.102	Consultation	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.103	Agency Roles in Consultation	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.104	Agency Responsibilities in Consultation.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.105	General Consultation Procedures	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.106	Consultation Procedures for Specific Major Activities.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.107	Consultation Procedures for Specific Routine Activities.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.108	Notification Procedures for Routine Activities.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.109	Conflict Resolution and Appeals to the Governor.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.110	Public Consultation Procedures	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.111	Enforceability of Design Concept and Scope and Project-Level Mitigation and Control Measures.	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].
20.2.99.112	Savings Provision	7/11/2014	6/18/2015	[Insert <b>Federal Register Citation</b> ].

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[FR Doc. 2015-13948 Filed 6-17-15; 8:45 am]

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**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 June 18, 2015.

**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](mailto: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.

\* \* \* \* \*

Dated: June 4, 2015. Oliver Potts, Deputy Executive Secretary, U.S. Department of Health and Human Services.

[FR Doc. 2015-14421 Filed 6-17-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1

Removal of Obsolete Provisions

AGENCY: Office of the Secretary, HHS. ACTION: Direct final rule.

SUMMARY: Much of the information set out in certain regulations regarding HHS's programs and activities is obsolete. Also, electronic resources are now available that did not exist when this part was first codified. This rule removes these obsolete regulations.

DATES: This action is effective August 17, 2015 without further action, unless adverse comment is received by July 20, 2015. If adverse comment is received, HHS will publish a timely cancellation of the action in the Federal Register.

ADDRESSES: Interested persons are invited to submit comments concerning this action. You may submit electronic comments to http://www.regulations.gov. Follow the "Submit a comment" instructions. Or, you may mail paper comments as follows: Madhura Valverde, Suite 639G, 200 Independence Avenue SW., Washington, DC 20201. (Please allow sufficient time for mailed comments to be received before the close of the comment period). If you wish to deliver paper comments in person or by courier, please call (202) 690-6827 or (202) 205-9165, to schedule the delivery with one of our staff members.

FOR FURTHER INFORMATION CONTACT: Madhura Valverde, Executive Secretary, U.S. Department of Health and Human Services, Washington, DC 20201 (madhura.valverde@hhs.gov).

SUPPLEMENTARY INFORMATION: The provisions of 45 CFR part 1, specifying the CFR locations of regulations for HHS's programs and activities, and regarding the subject matter of the Office of the Secretary regulations, have not been updated since 1987. These regulations have become obsolete and inaccurate. At the time they were added to the CFR, it was felt that this material would prove helpful to the public. However, the growth of electronic accessibility to regulations through such governmental sources as:

—Office of the Federal Register's (OFR) List of CFR Subjects

(www.archives.gov/federalregister/cfr/subjects.htm); —OFR's Electronic Code of Federal Regulations (www.ecfr.gov); —OFR's annual CFR ○ (www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR); —HHS's Web site (www.hhs.gov/regulations);

as well as numerous commercial web browsers, have greatly improved the public's access to, and ability to search our regulations. Because of this increased accessibility, and in response to Executive Order 13563, Sec. 6, which urges agencies to "repeal" existing regulations that are "outmoded", HHS is removing 45 CFR part 1.

Notice and comment are not required for this rule, because it affects agency organization, procedure, or practice under 5 U.S.C. 553(b)(A). Furthermore, HHS believes that there is good cause hereby to bypass notice and comment, and to proceed to a direct final rule, pursuant to 5 U.S.C. 553 (b)(B). The action is non-controversial, merely removing information from the CFR that is obsolete and inaccurate, and whose current locations are otherwise readily available. This rule posed no new substantive requirements on the public. Accordingly, HHS believes this direct final rule will not elicit any significant adverse comments, but if such comments are received HHS will publish a timely notice of withdrawal in the Federal Register.

Executive Order 12866

This action does not meet the criteria for a significant regulatory action as set out under Executive Order 12866, and review by the Office of Management and Budget has accordingly not been required.

Regulatory Flexibility Act

This action will not have a significant economic impact on a substantial number of small entities. Therefore, the regulatory flexibility analysis provided for under the Regulatory Flexibility Act is not required.

Paperwork Reduction Act

This action does not impose any information collection requirements under the Paperwork Reduction Act.

List of Subjects in 45 CFR Part 1

Code of Federal Regulations, Organization and functions (Government agencies).

For reasons set out in the preamble, and under the authority at 5 U.S.C. 301, HHS amends 45 CFR subchapter A by removing part 1.