Dated: May 9, 2011.

W.C. Early,

Acting Regional Administrator, Region III.

[FR Doc. 2011–12509 Filed 5–19–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2011–0030; FRL–9308–4]

Revisions to the California State Implementation Plan, Mojave Desert Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve revisions to the Mojave Desert Air Quality Management District (MDAQMD) portion of the California State Implementation Plan (SIP). These revisions concern negative declarations for volatile organic compound (VOC) source categories for the MDAQMD. We are proposing to approve these negative declarations under the Clean Air Act as amended in 1990 (CAA or the Act).

DATES: Any comments on this proposal must arrive by June 20, 2011.

ADDRESSES: Submit comments, identified by docket number EPA–R09–OAR–2011–0030, by one of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions.

2. *E-mail: steckel.andrew@epa.gov.*

3. *Mail or deliver:* Andrew Steckel (Air-4), U.S. Environmental Protection Agency Region IX, 75 Hawthorne Street, San Francisco, CA 94105–3901.

Instructions: All comments will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Information that you consider CBI or otherwise protected should be clearly identified as such and should not be submitted through *http://www.regulations.gov* or e-mail. *http://www.regulations.gov* is an "anonymous access" system, and EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send e-mail directly to EPA, your e-mail address will be automatically captured and included as part of the public comment. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: The index to the docket for this action is available electronically at *http://www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Cynthia Allen, EPA Region IX, (415) 947–4120, *allen.cynthia@epa.gov.*

SUPPLEMENTARY INFORMATION: This proposal addresses the following negative declarations listed in Table 1:

TABLE 1—SUBMITTED NEGATIVE DECLARATIONS

Local agency	Title	Adopted	Submitted
MDAQMD	Pneumatic Rubber Tire Manufacturing	01/22/07	07/11/07
MDAQMD	Large Petroleum Dry Cleaners	01/22/07	07/11/07
MDAQMD	Surface Coating of Cans	01/22/07	07/11/07
MDAQMD	Surface Coating of Coils	01/22/07	07/11/07
MDAQMD	Surface Coating Fabrics	01/22/07	07/11/07
MDAQMD	Surface Coating Operations at Automotive and Light Duty Truck Assembly Plants	01/22/07	07/11/07
MDAQMD	Surface of Coating of Large Appliances	01/22/07	07/11/07
MDAQMD	Surface of Coating of Magnet Wire	01/22/07	07/11/07
MDAQMD	Vacuum Producing Devices or Systems	01/22/07	07/11/07
MDAQMD	Leaks From Petroleum Refinery Equipment	01/22/07	07/11/07
MDAQMD	Process Unit Turnarounds	01/22/07	07/11/07
MDAQMD	Equipment Leaks From Natural Gas/Gasoline Processing Plants	01/22/07	07/11/07
MDAQMD	Synthesized Pharmaceutical Products	01/22/07	07/11/07
MDAQMD	Air Oxidation Process—SOCMI	01/22/07	07/11/07
MDAQMD	Polymer Manufacturing SOCMI and Polymer Manufacturing Equipment Leaks	01/22/07	07/11/07
MDAQMD	Reactor Processes and Distillation Operations in SOCMI	01/22/07	07/11/07
MDAQMD	Synthetic Organic Chemical Polymer and Resin Manufacturing	01/22/07	07/11/07
MDAQMD	Petroleum Refinery Equipment	08/23/10	10/22/10
MDAQMD	Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins	08/23/10	10/22/10
MDAQMD	Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.	08/23/10	10/22/10

In the Rules and Regulations section of this **Federal Register**, we are approving these negative declarations in a direct final action without prior proposal because we believe these negative declarations are not controversial. If we receive adverse comments, however, we will publish a timely withdrawal of the direct final rule and address the comments in subsequent action based on this proposed rule. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

We do not plan to open a second comment period, so anyone interested in commenting should do so at this time. If we do not receive adverse comments, no further activity is planned. For further information, please see the direct final action.

Dated: April 25, 2011.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2011–12364 Filed 5–19–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 10

RIN 0906–AA94

Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act (PHSA) "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B implemented a drug pricing program by which manufacturers who participate in Medicaid are required to sell covered outpatient drugs to particular covered entities listed in the statute and must agree to charge a price that will not exceed the amount determined under a statutory formula. The manufacturer's obligation to sell at no greater than the ceiling price extends only to covered outpatient drugs and does not apply to inpatient drugs. Covered entities are required to ensure that drugs purchased under 340B are used only for outpatients. The Patient Protection and Affordable Care Act expanded the types of covered entities eligible to participate in the 340B Drug Pricing Program (340B Program) under the PHSA to include certain free standing cancer hospitals, rural referral centers, sole community hospitals, critical access hospitals, and children's hospitals. Of these entities, children's hospitals were already eligible to participate in the 340B drug pricing program under the Deficit Reduction Act of 2005. The Health Care and Education Reconciliation Act (HCERA) (the Patient Protection and Affordable Care Act and HCERA collectively hereinafter will be referred to as the "Affordable Care Act"), as amended by the Medicare and Medicaid Extenders Act of 2010, contained a provision that limits the types of drugs that free standing cancer hospitals, rural referral centers, sole community hospitals and critical access hospitals could obtain through the 340B Program. Under the changes made by the Affordable Care Act, orphan drugs, when used for the rare condition or disease for which that orphan drug was designated under the Federal Food, Drug, and Cosmetic Act (FFDCA), are excluded from the definition of covered outpatient drug for the specified newly-eligible covered entity types for purposes of the 340B Program. This regulatory action details how these exclusions will be implemented under the 340B Program.

DATES: Comments on this proposed rule must be submitted by July 19, 2011.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AA94, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: opaorphan@hrsa.gov.* Include RIN 0906–AA94 in the subject line of the message.
- *Mail:* CDR Krista Pedley, Director, Office of Pharmacy Affairs (OPA), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Parklawn Building, Room 10C–03, Rockville, Maryland 20857.

All submissions received must include the agency name and RIN for this rulemaking. All comments received will be available for public inspection and copying without charge, including any personal information provided, at Parklawn Building, 5600 Fishers Lane, Room 10C–03, Rockville, Maryland 20857, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: CDR Krista Pedley at the mail address or by telephone at (301) 594–4353.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of the 340B Program is to permit covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No.102–384(II), at 12 (1992). The 340B Program was established by section 602 of the Veterans Health Care Act of 1992 (Pub. L. 102–585) and is codified as section 340B of the PHSA. Section 340B instructs HHS to enter into Pharmaceutical Pricing Agreements (PPA) with drug manufacturers. (42 U.S.C. 256b(a)). If manufacturers sign a PPA, they agree that the prices charged for covered outpatient drugs to covered entities (organizations eligible under section 340B to receive 340B discounted pricing) will not exceed defined ceiling prices, which are based on pricing data reported to the Centers for Medicare & Medicaid Services (CMS). The 340B ceiling price is calculated by subtracting the Unit Rebate Amount from the Average Manufacturer Price. Drugs purchased by covered entities through the 340B Program may not be sold or transferred to anyone other than the patients of the covered entities. Since 1992, the program has grown; there are currently over 16,000 participating covered entity sites in the 340B Program.

The Affordable Care Act introduced several changes to the 340B Program. The 340B Program has not previously published codified regulations on the operation of this program, instead relying on published program guidance documents, which were typically finalized after a notice and comment period. However, a number of the provisions of the Affordable Care Act necessitate the development and publication of regulations. This is the first of a series of regulations that will outline certain requirements in the 340B Program.

Section 7101 of the Affordable Care Act added several new categories of eligibility for program participants, allowing them to have access to 340B drug pricing except in the case of an orphan drug when used for a rare disease or condition. The entity types added to the list of eligible entities listed under 340B(a)(4) included: 340B(a)(4)(M) (children's hospitals and free-standing cancer hospitals), 340B(a)(4)(N) (critical access hospitals), and 340B(a)(4)(O) (rural referral centers and sole community hospitals). As amended by the Affordable Care Act, and section 204 of the Medicare and Medicaid Extenders Act of 2010 (Pub. L. 111–309), section 340B(e) of the PHSA (42 U.S.C. 256b(e)) states the following:

> • EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES—For covered entities described in subparagraph (M), (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term 'covered outpatient drug' shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.

Congress passed the Orphan Drug Act of 1983 to stimulate the development of drugs for rare diseases. The Food and Drug Administration (FDA), Office of Orphan Products Development, administers the Orphan Drug Act and reviews requests for designations. Orphan status designation by the FDA indicates that the drug has been found "promising" for treating a rare disease. The award of an orphan designation does not alter the standard regulatory requirements and process for obtaining