(*2*) A medication that—

(*i*) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a);

(*ii*) Which is referenced by at least one FDA-approved product that meets the criteria of paragraph (b)(1)(iv)(A)(*1*) of this section; and

(*iii*) Which is covered by a contracting strategy in place with pricing such that it is lower in cost than other generic sources.

(*3*) A medication that—

(*i*) Has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a); and

(*ii*) Has the same active ingredient or active ingredients, works in the same way and in a comparable amount of time, and is determined by VA to be substitutable for another medication that has been and remains approved by the FDA pursuant to FDCA section 505(b)(1) or PHSA section 351(a). This may include but is not limited to insulin and levothyroxine.

(*4*) A listed drug, as defined in 21 CFR 314.3, that has been approved under FDCA section 505(c) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

(B) *Tier 1 medication* means a multi-source medication that has been identified using the process described in paragraph (b)(2) of this section.

(C) *Tier 2 medication* means a multi-source medication that is not identified using the process described in paragraph (b)(2) of this section.

(D) *Tier 3 medication* means a medication approved by the FDA under a New Drug Application (NDA) or a biological product approved by the FDA pursuant to a biologics license agreement (BLA) that retains its patent protection and exclusivity and is not a multi-source medication identified in paragraph (b)(1)(iv)(A)(*3*) or (*4*) of this section.

(2) *Determining Tier 1 medications.* Not less than once per year, VA will identify a subset of multi-source medications as Tier 1 medications using the criteria below. Only medications that meet all of the criteria in paragraphs (b)(2)(i), (ii), and (iii) will be eligible to be considered Tier 1 medications, and only those medications that meet all of the criteria in paragraph (b)(2)(i) of this section will be assessed using the criteria in paragraphs (b)(2)(ii) and (iii).

(i) A medication must meet all of the following criteria:

(A) The VA acquisition cost for the medication is less than or equal to $10 for a 30-day supply of medication;

(B) The medication is not a topical cream, a product used to treat musculoskeletal conditions, an antihistamine, or a steroid-containing medication;

(C) The medication is available on the VA National Formulary;

(D) The medication is not an antibiotic that is primarily used for short periods of time to treat infections; and

(E) The medication primarily is used to either treat or manage a chronic condition, or to reduce the risk of adverse health outcomes secondary to the chronic condition, for example, medications used to treat high blood pressure to reduce the risks of heart attack, stroke, and kidney failure. For purposes of this section, conditions that typically are known to persist for 3 months or more will be considered chronic.

(ii) The medication must be among the top 75 most commonly prescribed multi-source medications that meet the criteria in paragraph (b)(2)(i) of this section, based on the number of prescriptions issued for a 30-day or less supply on an outpatient basis during a fixed period of time.

(iii) VA must determine that the medication identified provides maximum clinical value consistent with budgetary resources.

(3) *Information on Tier 1 medications.* Not less than once per year, VA will publish a list of Tier 1 medications in the **Federal Register** and on VA's Web site at *www.va.gov/health.*

(4) *Veterans Choice Program.* * * *

(5) *Copayment cap.* The total amount of copayments for medications in a calendar year for an enrolled veteran will not exceed $700.

* * * * *

[FR Doc. 2016–29515 Filed 12–9–16; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2014–0424; FRL–9956–35–Region 4]

Air Plan Approval/Disapproval; MS; Infrastructure Requirements for the 2012 $PM_{2.5}$ National Ambient Air Quality Standard

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve, in part, and disapprove in part, the State Implementation Plan (SIP) submission, submitted by the State of Mississippi, through the Mississippi Department of Environmental Quality (MDEQ), on December 11, 2015, to demonstrate that the State meets the infrastructure requirements of the Clean Air Act (CAA or Act) for the 2012 annual fine particulate matter ($PM_{2.5}$) national ambient air quality standard (NAAQS). The CAA requires that each state adopt and submit a SIP for the implementation, maintenance and enforcement of each NAAQS promulgated by EPA, which is commonly referred to as an ''infrastructure SIP submission.'' MDEQ certified that the Mississippi SIP contains provisions that ensure the 2012 Annual $PM_{2.5}$ NAAQS is implemented, enforced, and maintained in Mississippi. With the exception of the PSD permitting requirements and the interstate transport provisions, for which EPA is not acting upon, and the state board majority requirements respecting significant portion of income, for which EPA is finalizing disapproval, EPA is finalizing that portions of Mississippi's infrastructure submission, submitted to EPA on December 11, 2015, as satisfying certain required infrastructure elements for the 2012 Annual $PM_{2.5}$ NAAQS.

DATES: This rule will be effective January 11, 2017.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2014–0424. All documents in the docket are listed on the *www.regulations.gov* Web site. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to

schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Tiereny Bell, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Bell can be reached via electronic mail at *bell.tiereny@epa.gov* or via telephone at (404) 562–9088.

SUPPLEMENTARY INFORMATION:

I. Background and Overview

On December 14, 2012, EPA promulgated a revised primary annual $PM_{2.5}$ NAAQS. The standard was strengthened from 15.0 micrograms per cubic meter ($\mu g/m^3$) to 12.0 $\mu g/m^3$. *See* 78 FR 3086 (January 15, 2013). Pursuant to section 110(a)(1) of the CAA, states are required to submit SIPs meeting the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements such as requirements for monitoring, basic program requirements and legal authority that are designed to assure attainment and maintenance of the NAAQS. States were required to submit such SIPs for the 2012 Annual $PM_{2.5}$ NAAQS to EPA no later than December 14, 2015.

In a proposed rulemaking published on June 8, 2016 (81 FR 36848), EPA proposed to approve in part and disapprove in part Mississippi's December 11, 2015, SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS. In the June 8, 2016 proposed rulemaking, EPA proposed to disapprove the state board majority requirements respecting significant portion of income of 110(a)(2)(E)(ii). Also in the June 8, 2016 proposal, EPA did not propose any action regarding the preconstruction PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of (D)(i), and (J*),* and the interstate transport requirements of section 110(a)(2)(D)(i)(I) and (II) (prongs 1, 2, and 4). On March 18, 2015 (80 FR 14019), EPA approved Mississippi's December 11, 2015, infrastructure SIP submission regarding the PSD permitting requirements for major sources of sections 110(a)(2)(C), prong 3 of D(i), and (J) for the 2012 Annual $PM_{2.5}$ NAAQS. Therefore, EPA is not taking any action today pertaining to sections 110(a)(2)(C), prong 3 of D(i), and (J). Additionally, on May 25, 2016, EPA finalized a rule related to prong 4 of 110(a)(2)(D)(i)(II) of Mississippi's December 11, 2015, SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS and will therefore not be acting upon this element today. *See* 81 FR 33139. With respect to the interstate transport requirements of section 110(a)(2)(D)(i)(I) (prongs 1 and 2), EPA will consider these requirements in relation to Mississippi's 2012 Annual $PM_{2.5}$ NAAQS infrastructure submission in a separate rulemaking. The details of Mississippi's submission and the rationale for EPA's actions for this final rule are explained in the June 8, 2016, proposed rulemaking. Comments on the proposed rulemaking were due on or before July 8, 2016. EPA received no adverse comments on the proposed action.

II. Final Action

With regard to the state board majority requirements respecting significant portion of income, EPA is finalizing a disapproval of Mississippi's December 11, 2015, infrastructure submission. Under section 179(a) of the CAA, final disapproval of a submittal that addresses a requirement of a CAA Part D Plan or is required in response to a finding of substantial inadequacy as described in CAA section 110(k)(5) (SIP call) starts a sanctions clock. The portion of section 110(a)(2)(E)(ii) provisions (the provisions being proposed for disapproval in this notice) were not submitted to meet requirements for Part D or a SIP call, and therefore, no sanctions will be triggered. However, this final action will trigger the requirement under section 110(c) that EPA promulgate a Federal Implementation Plan (FIP) no later than two years from the date of the disapproval unless the State corrects the deficiency, and EPA approves the plan or plan revision before EPA promulgates such FIP. With the exceptions noted above, EPA is taking final action to approve Mississippi's infrastructure SIP submission for the 2012 Annual $PM_{2.5}$ NAAQS because the submission is consistent with section 110 of the CAA.

III. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a

report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by February 10, 2017. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: November 28, 2016.

Heather McTeer Toney,

Acting Regional Administrator, Region 4.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart Z—Mississippi

■ 2. Section 52.1270(e) is amended by adding a new entry ''110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual $PM_{2.5}$ NAAQS'' at the end of the table to read as follows:

§ 52. 1270 Identification of plan.

* * * * *

(e) * * *

EPA Approved Mississippi Non-Regulatory Provisions

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State submittal date/effective date	EPA approval date	Explanation
*	*	*	*	*
110(a)(1) and (2) Infrastructure Requirements for the 2012 Annual $PM_{2.5}$ NAAQS.	Mississippi	12/11/2015	12/12/2016, [Insert citation of publication in **Federal Register**].	With the exception of sections: 110(a)(2)(C) and (J) concerning PSD permitting requirements; 110(a)(2)(D)(i)(I) and (II) (prongs 1 through 4) concerning interstate transport requirements and the state board majority requirements respecting significant portion of income of section 110(a)(2)(E)(ii).

[FR Doc. 2016–29593 Filed 12–9–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 75

RIN 0991–AC06

Health and Human Services Grants Regulation

AGENCY: Division of Grants, Office of Grants Policy, Oversight, and Evaluation, Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: This final rule makes changes to the Department of Health and Human Services' (HHS) adoption of the Office of Management and Budget's (OMB) (''Uniform Administrative Requirements'') published on December 19, 2014 and the technical amendments published by HHS on January 20, 2016. HHS codified the OMB language, with noted modifications as explained in the preamble to the December promulgation. The HHS-specific modifications to the Uniform Administrative Requirements adopted prior regulatory language that was not in conflict with OMB's language, and provided additional guidance to the regulated community. Unlike all of the other modifications to the Uniform Administrative Requirements, these additional changes, although based on existing law or HHS policy, were not previously codified in regulation. HHS sought comment on these proposed changes in a notice of proposed rulemaking published on July 13, 2016. This final rule implements these regulatory changes. It also corrects one typographical error that was recently discovered in the most recent promulgation of the Uniform Administrative Requirements.

DATES: This rule is effective on January 11, 2017.

FOR FURTHER INFORMATION CONTACT: Quadira Dantro, MSHS, CRA at (202) 260–6825.

SUPPLEMENTARY INFORMATION:

Background

This final rule makes changes to the HHS's adoption of the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards published on December 19, 2014 (79 FR 75871) and the technical amendments published by HHS on January 20, 2016 (81 FR 3004). HHS codified the OMB language, with noted modifications, in 45 CFR part 75. Unlike all of the other modifications to the Uniform Administrative Requirements, these additional changes, although based on existing law or HHS policy, were not previously codified in regulation. This final rule implements these regulatory changes.

HHS received 24 relevant comments on the notice of proposed rulemaking, half of which were strongly supportive of the proposed rule. HHS addresses all of the comments below.

A. Nondiscrimination Provisions

Comment: HHS received twelve comments on these provisions, all of which were strongly supportive of the codification of the nondiscrimination provisions in HHS awards and the recognition of same-sex marriages. Several of these supportive comments also provided additional areas for consideration specifically regarding the definition of discrimination on the basis of sex. Collectively, the comments indicated that HHS should define discrimination on the basis of sex explicitly to include discrimination on