

recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: May 20, 2021.

**Debra H. Thomas,**

*Acting Regional Administrator, Region 8.*

[FR Doc. 2021–11191 Filed 5–27–21; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 52 and 70

[EPA–R04–OAR–2020–0461; FRL–10024–40–Region 4]

### Air Plan and Operating Permit Program Approval; Kentucky; Public, Affected State, and EPA Review

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to approve changes to the Kentucky State Implementation Plan (SIP) and the Kentucky Title V Operating Permit Program (Title V) submitted by the Commonwealth of Kentucky, through the Energy and Environment Cabinet (Cabinet) on August 12, 2020, and March 29, 2021. These revisions address the public notice rule provisions for the New Source Review (NSR), Federally Enforceable State Operating Permits (FESOP) and Title V programs of the Clean Air Act (CAA or Act) by providing for electronic notice (“e-notice”) and removing the mandatory requirement to provide public notice of a draft air permit in a newspaper. EPA is proposing to approve these changes as they are consistent with the Clean Air Act (CAA or Act) and implementing federal regulations.

**DATES:** Comments must be received on or before June 28, 2021.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–R04–OAR–2020–0461 at [www.regulations.gov](http://www.regulations.gov). Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from [Regulations.gov](http://Regulations.gov). EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points

you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit [www2.epa.gov/dockets/commenting-epa-dockets](http://www2.epa.gov/dockets/commenting-epa-dockets).

#### FOR FURTHER INFORMATION CONTACT:

Sarah LaRocca, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8994. Ms. LaRocca can also be reached via electronic mail at [larocca.sarah@epa.gov](mailto:larocca.sarah@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On October 5, 2016, EPA finalized revised public notice provisions for the NSR, Title V, and Outer Continental Shelf permitting programs of the CAA. See 81 FR 71613 (October 18, 2016). These rule revisions removed the mandatory requirement to provide public notice of permitting actions through publication in a newspaper and allow for internet e-notice as an option for permitting authorities implementing their own EPA-approved SIP rules and Title V rules, such as Kentucky’s EPA-approved permitting programs. Permitting authorities are not required to adopt e-notice. Nothing in the revised rules prevents a permitting authority with an EPA-approved permitting program from continuing to use newspaper notification and/or from supplementing e-notice with newspaper notification and/or additional means of notification. For the noticing of draft permits issued by permitting authorities with EPA-approved programs, the rule requires the permitting authority to use “a consistent noticing method” for all permit notices under the specific permitting program. When e-notice is provided, EPA’s rule requires electronic access (e-access) to the draft permit for the duration of the public comment period.

EPA anticipates that e-notice, which is already being practiced by many permitting authorities, will enable permitting authorities to communicate permitting and other affected actions to the public more quickly and efficiently and will provide cost savings over newspaper publication. EPA further anticipates that e-access will expand

access to permit-related documents. A full description of the e-notice and e-access provisions are contained in EPA’s October 18, 2016 rulemaking notice. See 81 FR 71613.

EPA is proposing to approve changes to 401 Kentucky Administrative Regulations (KAR) 52:100, *Public, affected state, and U.S. EPA review*, of the Kentucky SIP and Title V program, submitted by the Commonwealth on August 12, 2020, and March 29, 2021. The August 12, 2020, and March 29, 2021, SIP and Title V program revisions seek to establish a revised method of publication of public notices for public hearings and public comment periods, establish a revised method of notification of the opportunity to be placed on a mailing list of permit actions, change how documents related to permit proceedings will be available for public inspection, and make minor changes to 401 KAR 52:100 that do not alter the meaning of the regulation. The SIP revision updates the current SIP-approved version of 401 KAR 52:100 (Version 1) to Version 2. The Title V revision updates the approved version of 401 KAR 52:100 originally approved in the Kentucky Title V program in the same manner.<sup>1</sup>

##### II. EPA’s Analysis of Kentucky’s Submittals

The SIP and Title V program revisions contain changes to 401 KAR 52:100, *Public, affected state, and U.S. EPA review*, which establishes the procedures used by the Cabinet to provide for the review of federally-enforceable permits by the public, affected states, and EPA. Specifically, 401 KAR 52:100 applies to permit actions established in 401 KAR 52.020, *Title V Permits* and 401 KAR 52.030, *Federally-enforceable permits for non-major sources*.<sup>2</sup> In addition, the public

<sup>1</sup> EPA fully approved Kentucky’s title V permitting program in 2001. See 66 FR 54955 (October 31, 2001).

<sup>2</sup> 401 KAR 52:030 establishes requirements for sources that accept emission limitations to avoid major source NSR requirements under Title I of the Act or Operating Permit Program requirements under Title V of the Act. Sources subject to these types of permits restricting potential to emit (PTE), both for construction permitting of new or modified sources and operating permitting for existing major sources, are commonly referred to as synthetic minor sources. Kentucky prefers to distinguish between the Title V and Title I requirements that a source is attempting to avoid. Hence, they use the term “conditional major” for sources whose emissions are limited below the threshold for Title V, and “synthetic minor” for sources whose emissions are below the threshold for Title I. See “Cabinet Provisions and Procedures for Issuing Federally-Enforceable Permits for Nonmajor Sources,” which is incorporated by reference in Section 26 of 401 KAR 52:030. SIP-approved operating permit programs that restrict PTE

participation provisions of Kentucky's major source NSR permitting programs at 401 KAR 51:017, *Prevention of significant deterioration of air quality* (PSD), and 401 KAR 52:052, *Review of new sources in or impacting upon nonattainment areas* (addressing nonattainment new source review (NNSR)) cross reference 52 KAR 52:100. Specifically, Kentucky's PSD rules at 401 KAR 51:017, Section 5, *Exclusions from Increment Consumption*; Section 10, *Air Quality Models*; Section 14, *Sources Impacting Class I Areas*; Section 15, *Public Participation*; and Section 20, *Plant-wide Applicability Limit Provisions*, cite to 401 KAR 52:100 and to 40 CFR 51.166(q). Kentucky's NNSR rules at 401 KAR 51:052, Section 7(5)(f), *Source Obligation*; Section 10(3), *Federal land manager notification*; Section 10(4), *Public participation*; and Section 11, *Plant-wide Applicability Limit Provisions*, cite to 401 KAR 52:100 and to 40 CFR 52.21(4) (to the extent that 401 KAR 52:100 procedures do not apply).

In this proposed action, EPA is proposing to approve the following changes to 401 KAR 52:100. In Section 2, "Public Comment Period," Section 3, "Public Hearing," and Section 4, "Public Notice," the Cabinet is replacing the public notice method for the aforementioned permit programs from newspaper publication to website notification at <http://eec.ky.gov>. This method of notification is consistent with the public availability of information requirements for permits under 40 CFR 51.161, 51.166(q), 51.165(i), and 70.7 and the criteria for FESOP programs (see 54 FR 27274 (June 28, 1989)) (hereinafter FESOP Guidance). Additionally, this regulation allows the Cabinet to provide further notice in newspapers, newsletters, and press releases under Section 4(2).

Section 7, "Mailing List," is updated to require the Cabinet to notify persons of the opportunity to be on a mailing list to receive notification of permit actions via the Cabinet's website, rather than notification through hard copy publications.

Section 8, "Public Inspection of Documents," is also updated to require the Cabinet to post draft permits on the Cabinet's website for the duration of the public comment period. The revision to

primarily to avoid major source operating permitting under title V are commonly referred to as FESOP programs. The FESOP program is a voluntary mechanism for states to create federally enforceable restrictions on PTE to avoid major source permitting requirements, such as the title V operating permit program, and there are no specific CAA provisions or federal regulations regarding the issuance of synthetic minor or conditional major operating permits.

Section 8 deletes the requirement that the permit application, draft permit, and supporting material information be available for public inspection in local public libraries and county clerk offices, but retains the requirement that, during the public comment period, all non-confidential information contained in the permit application, draft permit, and supporting materials be made available at the main office of the Division of Air Quality and the Division for Air Quality Regional office having jurisdiction over the source. As described above, posting draft permits on a designated website is required for consistency under the federal rules when e-notice is provided.

In addition, the submission contains minor textual changes to provide clarity and greater consistency. These textual revisions include: updating references to the Cabinet, Division for Air Quality, and regional offices; language changes for clarity and consistency such as changing "specified" to "established" and adding "public" before references to notice and hearings; clarifying that confidential information refers to confidential business information (CBI) under 40 CFR part 2 and 400 KAR 1:060 in Section 5(11)(b); and clarifying that the Cabinet will issue a revised permit upon receipt of EPA objection under Section 10(9)(c)(2). It does not change substantive elements of the content of such notifications or time periods associated with notifications. EPA is proposing to approve these revisions because the revisions are consistent with the SIP revision requirements of CAA section 110, the Title V program revision requirements of 40 CFR 70.4, and EPA's permitting requirements for public participation.

### III. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference 401 KAR 52:100, *Public, affected state, and U.S. EPA review*, Version 2, state effective June 2, 2020, into the Kentucky SIP, as well as the State's federally approve title V program. The proposed incorporation includes minor textual changes and establishes a revised means of publication for public notices for public hearing, public comment periods, and the opportunity to join mailing lists, and a revised means to inspect documents related to permit proceedings. EPA has made, and will continue to make, these materials generally available through [www.regulations.gov](http://www.regulations.gov) and at the EPA Region 4 office (please contact the

person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

### IV. Proposed Action

EPA is proposing to approve the changes to 401 KAR 52:100, *Public, affected state, and U.S. EPA review*, of the Kentucky SIP and Title V program, as submitted on August 12, 2020, and March 29, 2021, for the reasons stated above.

### V. Statutory and Executive Order Reviews

In reviewing SIP and Title V submissions, EPA's role is to approve such submissions, provided that they meet the criteria under the CAA, and EPA's implementing regulations. This action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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 1955 (Pub. L. 104-4);
- Does not have Federalism implications as specified in the 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). The SIP is not approved to apply on any Indian reservation land or any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the SIP-related rules do 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.

Furthermore, the proposed rules regarding Title V Operating Permit programs do not have tribal implications because they are not approved to apply to any source of air pollution over which an Indian Tribe has jurisdiction, nor will these proposed rules impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects

##### 40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Reporting and recordkeeping requirements.

##### 40 CFR Part 70

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Operating Permits, Reporting and recordkeeping requirements.

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

Dated: May 20, 2021.

**John Blevins,**

*Acting Regional Administrator, Region 4.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 433, 438, 447, and 456

[CMS-2482-P2]

RIN 0938-AT82

#### Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements; Delay of Effective Date for Provision Relating to Manufacturer Reporting of Multiple Best Prices Connected to a Value Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule proposes to delay for 6 months the January 1, 2022 effective date for amendatory instruction 10.a., which addresses the reporting by manufacturers of multiple best prices connected to a value based purchasing arrangement, of the final rule entitled, “Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements”, published in the December 31, 2020 **Federal Register**. This proposed rule also proposes to delay for 2 years the April 1, 2022 effective date of inclusion (inclusion date) for U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands) in the amended regulatory definitions of “States” and “United States” for purposes of the Medicaid Drug Rebate Program (MDRP), adopted in the interim final rule with comment period entitled, “Medicaid Program; Covered Outpatient Drug; Further Delay of Inclusion of Territories in Definitions of States and United States”, published in the November 25, 2019 **Federal Register** to April 1, 2024. In the alternative, we are proposing to finalize an inclusion date that may be earlier than April 1, 2024, but not before January 1, 2023, based on public comments received. We are requesting

public comment on the proposed delays of applicable effective date and inclusion date discussed in greater detail below.

**DATES:** To be assured consideration, comments on the proposals must be received at one of the addresses provided below by June 28, 2021.

**ADDRESSES:** In commenting, please refer to file code CMS-2482-P2.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2482-P2, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-2482-P2, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Christine Hinds, (410) 786-4578; Wendy Tuttle, (410) 786-8690.

#### **SUPPLEMENTARY INFORMATION:**

*Inspection of Public Comments:* All comments received before the close of the applicable comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the applicable comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.