Docket No. FDA–2020–P–1181). This petition (Parent petition) was routed for review and response after FDA's March 27, 2020, letter granting JRC's request for a stay in part. Although filed by different parties, the Parent petition requested the same action as the JRC petition and did not necessitate a different response or change in the stay FDA granted in response to the JRC petition. Both petitions request a stay based on all four criteria for a mandatory stay or, alternatively, based on being ''in the public interest and in the interest of justice'' for a discretionary stay (§ 10.35 (21 CFR 10.35(e))). Because the petitions request the same action for substantially similar reasons, FDA has determined that its March 27, 2020, response to the JRC petition is equally applicable to the Parent petition. FDA notes that both sets of petitioners filed legal challenges to the ban in the U.S. Court of Appeals for the D.C. Circuit, which challenges have now been consolidated before that court.

By a letter dated March 27, 2020, FDA responded to the JRC petition granting in part a discretionary temporary stay. As the letter states, it is in the public health interest and interest of justice to stay the compliance date for devices subject to the ban that are currently in use on specific individuals who would need to obtain a physician-directed transition plan to cease use of such devices. The stay is in the public interest and interest of justice because of the ongoing national emergency caused by ''severe acute respiratory syndrome coronavirus 2'' (SARS–CoV–2) and the disease it causes ''Coronavirus Disease 2019 (COVID–19).'' Specifically, the creation or implementation of a physician-directed transition plan has the potential to increase the risk of transmission or exposure to COVID–19, and it may divert healthcare delivery resources from other uses during the pandemic.

The stay is intended to remain in effect for the duration of the public health emergency related to COVID–19 declared by HHS, including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act (42 U.S.C. 247d(a)(2)). Once the public health emergency ends, FDA will substantively respond to the petitions, and issue another notification in the **Federal Register**, if necessary, in accordance with § 10.35. If the public health emergency ends while the consolidated legal challenge in the D.C. Circuit is still pending, the stay will continue in effect until: (1) FDA substantively responds to the petitions and (2) if FDA does not grant the petitions, the parties have had adequate time and reasonable opportunity to obtain a ruling from the D.C. Circuit regarding a stay of FDA's response to the petitions.

FDA's partial stay is limited to those devices currently in use on specific individuals who have or would need to obtain a physician-directed transition plan to cease use of such devices in order to comply with the final regulation banning ESDs. For all other devices, the ban became effective on, and required compliance by, April 6, 2020.

Dated: July 27, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16595 Filed 8–17–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 50

[Docket No. OAG 165; AG Order No. 4769–2020]

Prohibition on the Issuance of Improper Guidance Documents Within the Justice Department

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Interim final rule; request for comments.

SUMMARY: This rule codifies in the regulations of the Department of Justice (''Department'') the Memorandum for All Components from Attorney General Jefferson B. Sessions III titled, ''Prohibition on Improper Guidance Documents'' (Nov. 16, 2017), consistent with Executive Order 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents'' (Oct. 9, 2019).

DATES: *Effective date:* This rule is effective August 19, 2020. *Comments:* Comments are due on or before September 18, 2020.

ADDRESSES: To ensure proper handling of comments, please reference Docket No. OAG 165 on all electronic and written correspondence. The Department encourages the electronic submission of all comments through *https://www.regulations.gov* using the electronic comment form provided on that site. For easy reference, an electronic copy of this document is also available at that website. It is not necessary to submit paper comments that duplicate the electronic submission, as all comments submitted to *https://www.regulations.gov* will be posted for public review and are part of the official docket record. However, should you wish to submit written comments through regular or express mail, they should be sent to: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530. Comments received by mail will be considered timely if they are postmarked on or before September 18, 2020. The electronic Federal eRulemaking portal will accept comments until midnight Eastern Time at the end of that day.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at *https://www.regulations.gov.* Information made available for public inspection includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you wish to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not wish it to be posted online, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also locate all the personal identifying information that you do not want posted online in the first paragraph of your comment and identify what information you want the agency to redact. Personal identifying information identified and located as set forth above will be placed in the agency's public docket file, but not posted online.

If you wish to submit confidential business information as part of your comment but do not wish it to be posted online, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, the agency may choose not to post that comment (or to post that comment only partially) on *https://*

www.regulations.gov. Confidential business information identified and located as set forth above will not be placed in the public docket file, nor will it be posted online.

If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

II. Discussion

A. Attorney General Memorandum of November 16, 2017

In a memorandum to all components of the Department dated November 16, 2017, then-Attorney General Jefferson B. Sessions III reiterated the duty of the Department ''to uphold the laws of the United States and to ensure the fair and impartial administration of justice.'' Memorandum for All Components, ''Prohibition on Improper Guidance Documents,'' Nov. 16, 2017, *available at https://www.justice.gov/opa/press-release/file/1012271/download* (''Attorney General's memorandum''). The Attorney General's memorandum further stated that ''when the Department engages in regulatory activity, it should model the lawful exercise of regulatory power.'' *Id.*

In particular, the Attorney General's memorandum explained that, ''[i]n promulgating regulations, the Department must abide by constitutional principles and follow the rules imposed by Congress and the President. These principles and rules include the fundamental requirement that agencies regulate only within the authority delegated to them by Congress. They also include the Administrative Procedure Act's requirement to use, in most cases, notice-and-comment rulemaking when purporting to create rights or obligations binding on members of the public or the agency. Not only is notice-and-comment rulemaking generally required by law, but it has the benefit of availing agencies of more complete information about a proposed rule's effects than the agency could ascertain on its own, and therefore results in better decision making by regulators.'' *Id.*

The Attorney General's memorandum further explained that, ''[n]ot every agency action is required to undergo notice-and-comment rulemaking. For example, agencies may use guidance and similar documents to educate regulated parties through plain-language restatements of existing legal requirements or provide non-binding advice on technical issues through examples or practices to guide the application or interpretation of statutes and regulations. But guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch. Nor should guidance create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.'' *Id.*

The Attorney General's memorandum acknowledged that ''the Department has in the past published guidance documents—or similar instruments of future effect by other names, such as letters to regulated entities—that effectively bind private parties without undergoing the rulemaking process.'' *Id.* However, it stated that, going forward, ''[t]he Department will no longer engage in this practice.'' *Id.* Effective immediately, the Attorney General directed Department components not to ''issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments).'' *Id.*

The Attorney General's memorandum also directed that, to avoid circumventing the rulemaking process, Department components must adhere to a set of defined principles when issuing guidance documents. *Id.* Subsequently, these principles were included in the Justice Manual at section 1–19.000. *See* Justice Manual, sec. 1–19.000, ''Limitation on Issuance of Guidance Documents,'' *available at https://www.justice.gov/jm/justice-manual.*

B. Executive Order 13891 of October 9, 2019

On October 9, 2019, President Donald J. Trump issued Executive Order 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents.'' Executive Branch agencies must follow the requirements and provisions prescribed therein to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them and that Americans have fair notice of their obligations.

Among its other provisions, Executive Order 13891 set forth a definition of ''guidance document'' and provided robust limitations and protections regarding Executive Branch agencies' issuance of guidance documents.

C. This Interim Rule

This rule codifies in the Statements of Policy portion of the Department's regulations, 28 CFR part 50, the principles set forth in both the Attorney General's memorandum, and section 1–19.000 of the Justice Manual, consistent with Executive Order 13891. The scope of this rulemaking is limited. The Department anticipates publishing a rulemaking in the future to implement the requirements and provisions of Executive Order 13891 that are not covered by this rulemaking.

III. Regulatory Certifications

A. Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, or practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. *See* 5 U.S.C. 553(a)(2), (b)(A), (d). However, the Department is, in its discretion, seeking public comment on this rulemaking.

B. Regulatory Flexibility Act

This rule will not have an impact on small entities because it pertains to personnel and administrative matters affecting the Department. A Regulatory Flexibility Analysis was not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. *See* 5 U.S.C. 601(2), 604(a).

C. Executive Orders 12866, 13563, and 13771 (Regulatory Planning and Review)

This rule has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation, and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1(b), General Principles of Regulation.

This rule is ''limited to agency organization, management, or personnel matters'' and thus is not a ''rule'' for purposes of review by the Office of Management and Budget (OMB), a determination in which OMB has concurred. *See* Executive Order 12866, sec. 3(d)(3). Accordingly this rule has not been formally reviewed by OMB.

This rule is not subject to the requirements of Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs,'' because it is not a significant regulatory action under Executive Order 12866.

D. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, ''Civil Justice Reform.''

E. Executive Order 13132 (Federalism)

This rule will not have substantial direct effects on the States, on the relationship between the national

government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, ''Federalism,'' the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

G. Congressional Review Act

This rule is not a major rule as defined by section 804 of the Congressional Review Act, 5 U.S.C. 804. This action pertains to agency management or personnel, and agency organization, procedure, or practice, and does not substantially affect the rights or obligations of non-agency parties. Accordingly, it is not a ''rule'' as that term is used by the Congressional Review Act, 5 U.S.C. 804(3)(B), (C), and the reporting requirement of 5 U.S.C. 801 does not apply.

H. Paperwork Reduction Act of 1995

This rule does not impose any new reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3521.

List of Subjects in 28 CFR Part 50

Administrative practice and procedure.

Accordingly, for the reasons set forth in the preamble, part 50 of chapter I of title 28 of the Code of Federal Regulations is amended as follows:

PART 50—STATEMENTS OF POLICY

■ 1. The authority citation for part 50 continues to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 1162; 28 U.S.C. 509, 510, 516, and 519; 42 U.S.C. 1921 *et seq.,* 1973c; and Pub. L. 107–273, 116 Stat. 1758, 1824.

■ 2. Section 50.26 is added to read as follows:

§ 50.26 Limitation on issuance of guidance documents.

(a) *General principles.* (1) The term ''guidance document'' means an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth

(i) A policy on a statutory, regulatory, or technical issue, or

(ii) An interpretation of a statute or regulation.

(2) The term ''guidance document'' does not include the following:

(i) Rules promulgated pursuant to notice and comment under section 553 of title 5, United States Code, or similar statutory provisions;

(ii) Rules exempt from rulemaking requirements under section 553(a) of title 5, United States Code;

(iii) Rules of agency organization, procedure, or practice;

(iv) Decisions of agency adjudications under section 554 of title 5, United States Code, or similar statutory provisions;

(v) Internal guidance directed to the issuing agency or other agencies that is not intended to have substantial future effect on the behavior of regulated parties;

(vi) Internal Executive Branch legal advice or legal opinions addressed to Executive Branch officials, *see* E.O. 13891 of October 9, 2019, sec. 2(b); or

(vii) Documents informing the public of the agency's enforcement priorities or factors the agency considers in exercising its prosecutorial discretion.

(3) An agency guidance document may not be used as a substitute for regulation and may not be used to impose new standards of conduct on persons outside the Executive Branch except as expressly authorized by law or as expressly incorporated into a contract.

(4) In accordance with the principles set forth in paragraphs (a)(1) through (3) of this section, except where expressly authorized by law or as expressly incorporated into a contract, Department components may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments). Likewise, except where expressly authorized by law or as expressly incorporated into a contract, Department components may not issue guidance documents that create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.

(b) *Compliance procedures.* To ensure compliance with this section, when issuing guidance documents, Department components must, except where expressly authorized by law or as expressly incorporated into a contract:

(1) Identify the documents as guidance, disclaim any force or effect of law, and avoid language suggesting that the public has obligations that go beyond those set forth in the applicable statutes and regulations;

(2) Clearly state that the documents do not bind the public, except as authorized by law or as incorporated into a contract;

(3) Avoid using the documents for the purpose of coercing persons or entities outside of the Executive Branch into taking any action or refraining from any action beyond what is required by the terms of the applicable statute or regulation;

(4) Avoid using mandatory language such as ''shall,'' ''must,'' ''required,'' or ''requirement'' to direct parties outside the Executive Branch to take or refrain from taking action except when restating—with citations to statutes, regulations, or binding judicial precedent—clear mandates contained in the statute, regulation, or binding judicial precedent; and

(5) Clearly state that noncompliance with voluntary standards will not, in itself, result in any enforcement action.

Dated: July 24, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–16473 Filed 8–18–20; 8:45 am]

BILLING CODE 4410–BB–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0223; FRL–10012–75–Region 1]

Air Plan Approval; Connecticut; Infrastructure State Implementation Plan Requirements for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving most of the elements of a State Implementation Plan (SIP) revision submitted by the State of Connecticut that addresses the infrastructure requirements of the Clean Air Act (CAA or Act), excluding the interstate transport provisions, for the 2015 ozone National Ambient Air Quality Standards (NAAQS). We are conditionally approving several elements of Connecticut's SIP revision regarding air quality modeling requirements.

The infrastructure requirements are designed to ensure that the structural