

implement and issue permits for HSWA requirements for which Ohio is not yet authorized. EPA has the authority to enforce state-issued permits after the State is authorized.

I. How does today's action affect Indian country (18 U.S.C. 1151) in Ohio?

Ohio is not authorized to carry out its hazardous waste program in Indian country within the State, which includes:

- All lands within the exterior boundaries of Indian reservations within or abutting the State of Ohio;
- Any land held in trust by the U.S. for an Indian tribe; and
- Any other land, whether on or off an Indian reservation, that qualifies as Indian country.

Therefore, this action has no effect on Indian country. EPA retains jurisdiction over Indian country and will continue to implement and administer the RCRA program on these lands.

J. What is codification and will EPA codify Ohio's hazardous waste program as proposed in this rule?

Codification is the process of placing citations and references to the State's statutes and regulations that comprise the State's authorized hazardous waste program into the Code of Federal Regulations. EPA does this by adding those citations and references to the authorized State rules in 40 CFR part 272. EPA is not proposing to codify the authorization of Ohio's changes at this time. However, EPA reserves the ability to amend 40 CFR part 272, subpart KK for the authorization of Ohio's program changes at a later date.

K. Statutory and Executive Order Reviews

The Office of Management and Budget (OMB) has exempted this action from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). This action proposes to authorize State requirements for the purpose of RCRA section 3006 and imposes no additional requirements beyond those imposed by State law. Therefore, this action is not subject to review by OMB. This action is not an Executive Order 13771 (82 FR 9339, February 3, 2017) regulatory action because actions such as today's proposed authorization of Ohio's revised hazardous waste program under RCRA are exempted under Executive Order 12866. Accordingly, I certify that this action will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this action

proposes to authorize pre-existing requirements under State law and does not impose any additional enforceable duty beyond that required by State law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538). For the same reason, this action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely proposes to authorize State requirements as part of the State RCRA hazardous waste program without altering the relationship or the distribution of power and responsibilities established by RCRA. This action also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant and it does not make decisions based on environmental health or safety risks. This action is not subject to Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

Under RCRA section 3006(b), EPA grants a state's application for authorization as long as the state meets the criteria required by RCRA. It would thus be inconsistent with applicable law for EPA, when it reviews a state authorization application, to require the use of any particular voluntary consensus standard in place of another standard that otherwise satisfies the requirements of RCRA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in proposing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of this action in accordance with the “Attorney General's Supplemental

Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings” issued under the executive order. This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). “Burden” is defined at 5 CFR 1320.3(b). Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Because this action proposes authorization of pre-existing State rules which are at least equivalent to, and no less stringent than existing federal requirements, and imposes no additional requirements beyond those imposed by State law, and there are no anticipated significant adverse human health or environmental effects, this proposed rule is not subject to Executive Order 12898.

List of Subjects in 40 CFR Part 271

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Authority: This action is issued under the authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: May 21, 2019.

Cheryl L. Newton,

Acting Regional Administrator, Region 5.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 721

[EPA–HQ–OPPT–2019–0263; FRL–9994–85]

RIN 2070–AB27

Significant New Use Rules on Certain Chemical Substances (19–2.B)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for 8 chemical substances which are the subject of premanufacture notices (PMNs). This action would require persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these 8 chemical substances for an activity that is designated as a significant new use by this proposed rule. If this proposed rule is made final, persons may not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice, and EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any actions as are required as a result of that determination.

DATES: Comments must be received on or before July 11, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0263, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: For technical information contact: Kenneth Moss, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-9232; email address: moss.kenneth@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information***A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to these proposed SNURs would need to certify their compliance with the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after July 11, 2019 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) and must comply with the export notification requirements in 40 CFR part 707, subpart D.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket.

Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background*A. What action is the Agency taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) for 8 chemical substances which were the subjects of PMNs P-16-425, P-18-125, P-18-228, P-18-234, P-18-270, P-18-322, P-19-4, and P-19-34. These proposed SNURs would require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

The record for the proposed SNURs on these chemicals was established as docket EPA-HQ-OPPT-2019-0263. That record includes information considered by the Agency in developing these proposed SNURs.

B. What is the Agency's authority for taking this action?

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors listed in Unit III. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B)(i) (15 U.S.C. 2604(a)(1)(B)(i)) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. TSCA prohibits such manufacturing or processing from commencing until EPA has conducted a review of the SNUN, made an appropriate determination on the SNUN, and taken such actions as are required in association with that determination (15 U.S.C. 2604(a)(1)(B)(ii)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

C. Applicability of General Provisions

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees

appear at 40 CFR part 700. Pursuant to § 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A) (15 U.S.C. 2604(a)(1)(A)). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1) (15 U.S.C. 2604(b) and 2604(d)(1)), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before the manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the **Federal Register**, a statement of EPA's findings.

III. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute significant new uses for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, and potential human exposures and environmental releases that may be associated with the conditions of use of the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

IV. Substances Subject to This Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for 8 chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance:

- PMN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Information identified by EPA that would help characterize the potential health and/or environmental effects of the chemical substances if a manufacturer or processor is considering submitting a SNUN for a significant new use designated by the SNUR.

This information may include testing not required to be conducted but which would help characterize the potential health and/or environmental effects of the PMN substance. Any recommendation for information identified by EPA was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the chemical substance. Further, any such testing identified by EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models. EPA also recognizes that whether testing/further information is needed will depend on the specific exposure and use scenario in the SNUN. EPA encourages all SNUN submitters to contact EPA to discuss any potential future testing. See Unit VII. for more information.

- CFR citation assigned in the regulatory text section of these proposed rules.

The regulatory text section of these proposed rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the proposed rules, may be claimed as CBI.

The chemical substances that are the subject of these proposed SNURs are undergoing premanufacture review. EPA has initially determined under TSCA section 5(a)(2), 15 U.S.C. 2604(a)(2), that certain changes from the intended conditions of use described in the PMNs could result in changes in the type or form of exposure to the chemical

substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances. Consequently, EPA is proposing to designate these changes as significant new uses.

PMN Number: P-16-425

Chemical name: Amino-silane (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a chemical reactant used in manufacturing a polymer. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for irritation, lung effects, developmental effects, neurotoxicity, liver effects and skin sensitization if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

1. Use other than as a chemical intermediate.

The proposed SNUR would designate as a "significant new use" the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity or pulmonary effects, reproductive/developmental toxicity, neurotoxicity and skin sensitization testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11258.

PMN Number: P-18-125

Chemical name: Oxoalkylcarboxylic acid, sodium salt (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a reagent in coating material. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for kidney toxicity, eye, skin and lung irritation and developmental toxicity if the chemical

substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture of the PMN substance in the United States (*i.e.*, import only); and
2. No use other than the confidential use described in the PMN.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of irritation and sensitization testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11260.

PMN Number: P-18-228

Chemical name: Branched alkenyl acid, alkyl ester, homopolymer (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a tackifier. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for eye irritation, neurotoxicity, systemic, blood, respiratory and cardiovascular effects and developmental toxicity if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No use other than the confidential use identified in the PMN; and
2. No manufacture, processing or use of the PMN substance in any manner that results in inhalation exposures.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity,

pulmonary effects, developmental toxicity, and neurotoxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11261.

PMN Number: P-18-234

Chemical name: Alkenoic acid, reaction products with bis substituted alkane and ether polyol (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a coating component. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for skin and eye irritation and sensitization if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

1. No use of the PMN substance involving spray application that results in inhalation exposures.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of skin irritation, eye damage and skin sensitization testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11262.

PMN Number: P-18-270

Chemical name: Ethanol, 2-butoxy-, 1,1'-ester (generic).

CAS number: Not available.

Basis for action: The PMN states that the uses of the substance will be as an active co-solvent for solvent-based coatings; a coalescent for industrial water-based coatings; a coupling agent and solvent in industrial cleaners, rust removers, hard surface cleaners and disinfectants; and a primary solvent in solvent-based silk screen printing inks. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for skin irritation, solvent neurotoxicity, immunotoxicity, and developmental, reproductive, liver and blood toxicity, if

the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No use of the PMN substance for other than the uses described in the PMN; and
2. No use of the PMN substance in a consumer product.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of toxicokinetics, specific target organ toxicity, skin irritation, and reproductive toxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11263.

PMN Number: P-18-322

Chemical name: Heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)- (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a fragrance ingredient in consumer products. Based on the physical/chemical properties of the PMN substance and test data on the PMN substance, EPA has identified concerns for skin irritation and sensitization and gastrointestinal tract effects, liver and thyroid toxicity and blood effects if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture of the PMN substance in the United States (*i.e.*, import only); and
2. No processing (formulation) to a concentration of greater than 5% of the PMN substance by weight.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed

SNUR. EPA has determined that the results of specific target organ toxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11264.

PMN Number: P-19-4

Chemical name: Aromatic dianhydride, polymer with aromatic diamine and heteroatom bridged aromatic diamine, reaction products with aromatic anhydride (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as molded parts and components. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for lung overload if the chemical substance is not used following the limitations noted. The conditions of use of the PMN substance as described in the PMN include the following protective measure:

1. No manufacture, processing or use of the PMN substance in any manner that results in inhalation exposures.

The proposed SNUR would designate as a "significant new use" the absence of this protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of pulmonary effects testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11265.

PMN Number: P-19-34

Chemical name: Metal, bis(2,4-pentanedionato-kO2,kO4)- (T-4)- (generic).

CAS number: Not available.

Basis for action: The PMN states that the generic (non-confidential) use of the substance will be as a contained use as a component of tires. Based on the physical/chemical properties of the PMN substance and Structure Activity Relationships (SAR) analysis of test data on analogous substances, EPA has identified concerns for eye irritation, blood, liver, kidney, GI and reproductive/developmental effects, neurotoxicity, immunotoxicity, and genetic toxicity if the chemical substance is not used following the limitations noted. The conditions of use

of the PMN substance as described in the PMN include the following protective measures:

1. No manufacture of the PMN substance in the United States (*i.e.*, import only); and

2. No use other than the confidential use described in the PMN including the engineering controls for processing and use as described in the PMN.

The proposed SNUR would designate as a "significant new use" the absence of these protective measures.

Potentially useful information: EPA has determined that certain information about the human health toxicity of the PMN substance may be potentially useful to characterize the health effects of the PMN substance if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this proposed SNUR. EPA has determined that the results of specific target organ toxicity, reproductive/developmental toxicity, and neurotoxicity testing would help characterize the potential health effects of the PMN substance.

CFR citation: 40 CFR 721.11266.

V. Rationale and Objectives of the Proposed Rule

A. Rationale

During review of the PMNs submitted for the chemical substances that are the subject of these proposed SNURs and as further discussed in Unit IV, EPA identified certain reasonably foreseen changes from the conditions of use identified in the PMNs and determined that those changes could result in changes in the type or form of exposure to the chemical substances and/or increased exposures to the chemical substances and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances.

B. Objectives

EPA is proposing SNURs for 8 specific chemical substances which are undergoing premanufacture review because the Agency wants to achieve the following objectives with regard to the significant new uses that would be designated in this proposed rule:

- EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.

- EPA would be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use.

The Agency will either determine under section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a proposed SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the internet at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/index.html>.

VI. Applicability of the Proposed Rules to Uses Occurring Before the Effective Date of the Final Rule

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule were undergoing premanufacture review at the time of signature of this proposed rule and were not on the TSCA Inventory. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for the chemical substances subject to these proposed SNURs, EPA concludes that the proposed significant new uses are not ongoing.

EPA designates June 6, 2019 as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who begin commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under section 5 allowing manufacture or processing to proceed.

VII. Development and Submission of Information

EPA recognizes that TSCA section 5 does not require development of any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, order or consent agreement under TSCA section 4 (15 U.S.C. 2603), then TSCA section 5(b)(1)(A) (15 U.S.C. 2604(b)(1)(A)) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol selection. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h).

The potentially useful information described in Unit IV. may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so

that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

VIII. SNUN Submissions

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710–25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40 and 721.25. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

IX. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket under docket ID number EPA–HQ–OPPT–2019–0263.

X. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review

This proposed rule would establish SNURs for 8 new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

According to the PRA, 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA,

unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070–0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that promulgation of this proposed SNUR would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of

SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018, only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the **Federal Register** of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

D. Unfunded Mandates Reform Act (UMRA)

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this proposed rule. As such, EPA has determined that this proposed rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1531-1538 *et seq.*).

E. Executive Order 13132: Federalism

This action would not have a substantial direct effect on 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This proposed rule would not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This proposed rule would not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the

requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

In addition, since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

List of Subjects in 40 CFR Part 721

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: May 31, 2019.

Tala Henry,
Deputy Director, Office of Pollution Prevention and Toxics.

Therefore, it is proposed that 40 CFR part 721 be amended as follows:

PART 721—[AMENDED]

■ 1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add §§ 721.11258 and 721.11260 through 721.11266 to subpart E to read as follows:

Subpart E—Significant New Uses for Specific Chemical Substances
Sec.

- 721.11258 Amino-silane (generic).
- 721.11260 Oxoalkylcarboxylic acid, sodium salt (generic).
- 721.11261 Branched alkenyl acid, alkyl ester, homopolymer (generic).
- 721.11262 Alkenoic acid, reaction products with bis substituted alkane and ether polyol (generic).
- 721.11263 Ethanol, 2-butoxy-, 1,1'-ester (generic).
- 721.11264 Heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)- (generic).
- 721.11265 Aromatic dianhydride, polymer with aromatic diamine and heteroatom bridged aromatic diamine, reaction products with aromatic anhydride (generic).
- 721.11266 Metal, bis(2,4-pentanedionato-kO₂,kO₄)- (T-4)- (generic).

Subpart E—Significant New Uses for Specific Chemical Substances

§ 721.11258 Amino-silane (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amino-silane (PMN P-16-425) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(g).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i), are applicable to manufacturers and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11260 Oxoalkylcarboxylic acid, sodium salt (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as oxoalkylcarboxylic acid, sodium salt (P-18-125) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in

§ 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11261 Branched alkenyl acid, alkyl ester, homopolymer (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as branched alkenyl acid, alkyl ester, homopolymer (P-18-228) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(j). It is a significant new use to manufacture, process or use the substance in any manner that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

§ 721.11262 Alkenoic acid, reaction products with bis substituted alkane and ether polyol (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as alkenoic acid, reaction products with bis substituted alkane and ether polyol (P-18-234) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* It is a significant new use to use the substance involving spray application that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part

apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), (j) and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11263 Ethanol, 2-butoxy-, 1,1'-ester (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as ethanol, 2-butoxy-, 1,1'-ester (P-18-270) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance for other than an active co-solvent for solvent-based coatings; a coalescent for industrial water-based coatings; a coupling agent and solvent for industrial cleaners, rust removers, hard surface cleaners and disinfectants; and a primary solvent in solvent-based silk screen printing inks.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11264 Heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)- (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as heteromonocycle, 4,6-dimethyl-2-(1-phenylethyl)- (P-18-322) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to process (formulate) the substance to a concentration of greater than 5% by weight.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11265 Aromatic dianhydride, polymer with aromatic diamine and heteroatom bridged aromatic diamine, reaction products with aromatic anhydride (generic).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as aromatic dianhydride, polymer with aromatic diamine and heteroatom bridged aromatic diamine, reaction products with aromatic anhydride (P-19-4) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* It is a significant new use to manufacture, process or use of the substance in any manner that results in inhalation exposures.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

§ 721.11266 Metal, bis(2,4-pentanedionato-kO2,kO4)- (T-4)- (generic).

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance generically identified as metal, bis(2,4-pentanedionato-kO2,kO4)- (T-4)- (P-19-34) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, Commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j). It is a significant new use to process or use the substance without the engineering controls described in the premanufacture notice.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitations or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

[FR Doc. 2019-12115 Filed 6-10-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS-3295-RCN]

RIN 0938-AS21

Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Extension of Timeline for Publication of the Final Rule

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of timeline for publication of a final rule.

SUMMARY: This document announces the extension of the timeline for publication of the “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” final rule. We are issuing this document in accordance with section 1871(a)(3)(B) of the Social Security Act (the Act), which requires notice to be provided in the **Federal Register** if there are exceptional circumstances that cause us to publish a final rule more than 3 years after the publication date of the proposed rule. In this case, the complexity of the rule, its substantive nature, and the scope of comments received all warrant the extension of the timeline for publication.

DATES: As of June 7, 2019, the timeline for publication of the final rule to

finalize the provisions of the June 16, 2016 proposed rule (81 FR 39447) is extended until June 16, 2020.

FOR FURTHER INFORMATION CONTACT: CAPT Scott Cooper, USPHS, (410) 786-9465.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1871(a)(3)(A) of the Social Security Act (the Act) requires the Secretary of the Department of Health and Human Services (the Secretary), in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of a final rule based on the previous publication of a proposed rule or an interim final rule.

Section 1871(a)(3)(B) of the Act allows the timeline for publishing Medicare final regulations to vary based on the complexity of the regulation, the number and scope of comments received, and other related factors. The timeline for publishing the final rule, however, cannot exceed 3 years from the date of publishing the proposed regulation unless there are exceptional circumstances. The Secretary may extend the initial targeted publication date of the final rule if the Secretary provides public notice thereof, including a brief explanation of the justification for the variation, no later than the rule’s previously established proposed publication date.

After consultation with the Director of OMB, the Department of Health and Human Services (HHS), through the Centers for Medicare & Medicaid Services (CMS), published a notice in the December 30, 2004 **Federal Register** (69 FR 78442) establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

II. Notice of Continuation

Sections 1861(e)(1) through (8) of the Act provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, Conditions of Participation (CoPs) for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii)

and § 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

On May 26, 1993, CMS published a final rule in the **Federal Register** entitled “Medicare Program; Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCCHs)” (58 FR 30630) that implemented sections 6003(g) and 6116 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 and section 4008(d) of OBRA 1990. That rule established requirements for the EACH and RPCCH providers that participated in the seven-state demonstration program that was designed to improve access to hospital and other health services for rural residents.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated and certified as a Critical Access Hospital (CAH). CAHs participating in the MRHFP must meet the conditions for designation specified in the statute under section 1820(c)(2)(B) of the Act, and to be certified must also meet other criteria the Secretary may require, under section 1820(e)(3) of the Act. Under this authority, the Secretary has established regulatory requirements that a CAH must meet to participate in Medicare at 42 CFR part 485, subpart F.

In the June 16, 2016 **Federal Register** (81 FR 39447), we published a proposed rule entitled, “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care,” which would update the requirements that hospitals and CAHs must meet to participate in the Medicare and Medicaid programs. Consistent with section 1871(a)(3)(B) of the Act, the final rule for the June 16, 2016 proposed rule was to be published by June 14, 2019.

The revisions contained in the June 16, 2016 proposed rule were intended to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns. In response to the proposed rule, we received 200 public comments. Commenters included individuals, healthcare professionals and corporations, national associations and coalitions, state health departments, patient advocacy organizations, and individual facilities that would be impacted by the regulation. Generally, most comments centered on expressing