

that it receives from the final recovery or disposal facility within one year of shipment delivery to the final recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1, or one of disposal operations D1 through D12, or DC1 to DC2, to the competent authority of the country of export that controls the shipment as an export of hazardous waste, and on or after the electronic import-export reporting compliance date, to EPA electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. The recovery and disposal operations in this paragraph are defined in 40 CFR 262.81.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 7. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

■ 8. Revise § 265.12(a)(4)(ii) to read as follows:

§ 265.12 Required notices.

(a) * * *

(4) * * *

(ii) If the facility performed any of recovery operations R12, R13, or RC3, or disposal operations D13 through D15, promptly send copies of the confirmation of recovery or disposal that it receives from the final recovery or disposal facility within one year of shipment delivery to the final recovery or disposal facility that performed one of recovery operations R1 through R11, or RC1, or one of disposal operations D1 through D12, or DC1 to DC2, to the competent authority of the country of export that controls the shipment as an export of hazardous waste, and on or after the electronic import-export reporting compliance date, to EPA electronically using EPA's Waste Import Export Tracking System (WIETS), or its successor system. The recovery and disposal operations in this paragraph are defined in 40 CFR 262.81.

[FR Doc. 2021-21417 Filed 9-30-21; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[EPA-HQ-OPPT-2020-0474; FRL-8204-02-OCSPPT]

RIN 2070-AB11

Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants; Extension of Submission Deadline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; extension of submission deadline.

SUMMARY: EPA is amending the deadline for reporting pursuant to the Toxic Substances Control Act (TSCA) Health and Safety Data Reporting rule, which requires manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. Specifically, EPA will be amending the deadline from September 27, 2021 to December 1, 2021 for 20 of the 50 chemical substances and to January 25, 2022 for 30 of the 50 chemical substances. The Health and Safety Data Reporting Rule, promulgated pursuant to TSCA section 8(d), requires manufacturers (including importers) of certain chemical substances to submit lists and copies of certain unpublished health and safety studies to EPA.

DATES: This final rule is effective October 1, 2021.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2020-0474, is available at <https://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC.

Please note that due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on the EPA/DC and docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Virginia Lee, Data Collections Branch, Data Gathering and Analysis Division (7410M), Office of Pollution Prevention and Toxics, Environmental Protection

Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-4142; email address: lee.virginia@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 (defined by statute to include import) any of the chemical substances that are listed in 40 CFR 716.120(d) of the regulatory text of this document. 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: Chemical manufacturers (including importers), (NAICS codes 325 and 324110), e.g., persons who manufacture (defined by statute to include import) one or more of the subject chemical substances.

B. What action is the Agency taking?

EPA promulgated a final rule in the **Federal Register** of June 29, 2021 (86 FR 34147) (FRL-10020-38) to require manufacturers (including importers) of 50 specified chemical substances to report certain lists and copies of unpublished health and safety studies to EPA. The chemical substances subject to this rule are listed in this document and consist of the 20 designated by EPA as high-priority substances and the 30 organohalogen flame retardants being evaluated for risks by the Consumer Product Safety Commission (CPSC) under the Federal Hazardous Substances Act (FHSA). The Agency is extending the submission deadline established in that final rule from September 27, 2021 to December 1, 2021 for the following chemicals:

- Ethylene Dibromide
- 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)
- Tris(2-chloroethyl) phosphate (TCEP)
- Phthalic Anhydride
- p-Dichlorobenzene
- o-Dichlorobenzene
- Phosphoric acid, triphenyl ester (TPP)
- Di-ethylhexyl phthalate (DEHP)
- 1,2-Dichloroethane
- trans-1,2-Dichloroethylene
- 1,1,2-Trichloroethane
- 1,2-Dichloropropane

- 1,1-Dichloroethane
 - 1,3-Butadiene
 - Formaldehyde
 - Dibutyl phthalate (DBP)
 - Butyl benzyl phthalate (BBP)
 - Di-isobutyl phthalate
 - Dicyclohexyl phthalate
 - 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA)
- EPA is also extending the deadline established in the June 29, 2021 final rule from September 27, 2021 to January 25, 2022 for the following chemicals:
- Bis(2-ethylhexyl) tetrabromophthalate
 - Bis(hexachlorocyclopentadieno) cyclooctane
 - 1,2-Bis(2,4,6-tribromophenoxy)ethane
 - 1,1'-Ethane-1,2-diylbis(pentabromobenzene)
 - 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate
 - 2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate
 - 2,2'-[(1-Methylethylidene)bis(2,6-dibromo-4,1-phenylene)oxymethylene]bis[oxirane]
 - Mixture of chlorinated linear alkanes C14–17 with 45–52% chlorine
 - N,N-Ethylene-bis(tetrabromophthalimide)
 - Pentabromochlorocyclohexane
 - (Pentabromophenyl)methyl acrylate
 - Pentabromotoluene
 - Perbromo-1,4-diphenoxybenzene
 - Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester
 - Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester
 - Propanoic acid, 2-bromo-, methyl ester
 - Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)
 - Tetrabromobisphenol A-bis(2-hydroxyethyl) ether
 - Tetrabromobisphenol A diallyl ether
 - Tetrabromobisphenol A dimethyl ether
 - 2,4,6-Tribromoaniline
 - 1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene
 - Tris(2-chloroethyl)phosphite
 - Tris(1-chloro-2-propyl)phosphate
 - Tris(2-chloro-1-propyl)phosphate
 - Tris(2,3-dibromopropyl)phosphate
 - 1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
 - Tris(1,3-dichloro-2-propyl)phosphate
 - Tris(tribromoneopentyl)phosphate
 - 2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine

C. Why is the Agency taking this action?

The Agency is taking this action to provide additional time for the regulated community to familiarize themselves with new TSCA Health and

Safety Data Reporting requirements. EPA has not added chemicals to the TSCA section 8(d) rule in a manner that would affect a large group of stakeholders since 2006, for the orphan High Production Volume chemicals. With respect to the timing of this action, the need for the Agency to extend the deadline arose, in part, as a result of receiving a sizable number of requests to extend the reporting deadline.

Additionally, the Agency recognizes that complications exist for certain entities subject to this rule resulting from the COVID-19 pandemic, which can present challenges to accessing records that may only be available in hard copy formats (e.g., microfiche).

EPA therefore believes it is appropriate to extend the reporting period to allow the regulated community additional time for data reporting. EPA is making available a historic question and answer document about reporting under TSCA 8(d) and additional content on its web page for the rulemaking (available at <https://www.epa.gov/chemicals-under-tsca/health-and-safety-data-reporting-addition-20-high-priority-substances-and-30>), providing reporting entities additional time to review these materials and prepare any necessary submissions to improve reporting quality for this rule.

EPA's timeline for risk evaluations under TSCA section 6 necessitates that data received via the TSCA section 8(d) action be received in time for use in risk evaluations for chemical substances that have been designated as high-priority substances. Thus, EPA is limiting the deadline extension to December 1, 2021 for these chemical substances. Receiving TSCA section 8(d) submissions on these high-priority substances by December 1, 2021 will ensure that such information will be received in time for use in risk evaluations on these chemical substances. For the remaining organohalogen flame retardants subject to the rule, EPA is extending the deadline to January 25, 2022.

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

EPA promulgated the Health and Safety Data Reporting rule under TSCA section 8(d) (15 U.S.C. 2607(d)), and it is codified at 40 CFR part 716. EPA is using this TSCA section 8(d) rule in accordance with 40 CFR 716.105 to gather information on chemical substances. Under section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), an agency may issue a final rule without providing notice and an opportunity for public comment if it for good cause finds that

notice and public procedures are impracticable, unnecessary, or contrary to the public interest. In this instance, the Agency finds that notice and public comment procedures are unnecessary because this is merely an extension of the reporting period that does not alter the substantive TSCA section 8(d) reporting requirements in any way and are impracticable because there is insufficient time for notice and comment on an extension to the deadline prior to the reporting deadline, and EPA only became aware of the need for the extension upon receiving numerous requests recently. The Agency believes the extension will not result in a significant delay in the processing and availability of information to EPA for TSCA section 6 risk evaluations or to Consumer Product Safety Commission's (CPSC) evaluation for risks under the Federal Hazardous Substances Act (FHSA). Receiving TSCA section 8(d) submissions pursuant to these deadlines (i.e., December 1, 2021 for the high-priority substances and January 25, 2022 for the Organohalogen Flame Retardants) will ensure that such information will be received in time for use in these respective activities (i.e., evaluations pursuant to TSCA and FHSA). Further, any impact on the regulated community is expected to be beneficial to the public interest given that the extension provides additional time to submit complete and accurate unpublished health and safety studies to EPA.

This final rule is effective immediately upon publication. Section 553(d)(1) of the Administrative Procedure Act, 5 U.S.C. 553(d)(1), provides that final rules shall not become effective until 30 days after publication in the **Federal Register** "except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction." The purpose of this provision is to "give affected parties a reasonable time to adjust their behavior before the final rule takes effect." *Omnipoint Corp. v. Fed. Comm'n Comm'n*, 78 F.3d 620, 630 (D.C. Cir. 1996); see also *United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. EPA has determined that this rule relieves a restriction because it provides manufacturers (including importers) additional time to comply with the Health and Safety Data Reporting rule.

II. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

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

The Office of Management and Budget (OMB) has exempted actions under TSCA section 8(d) related to the Health and Safety Data Reporting rule from the requirements of Executive Order 12866 (58 FR 51735, October 4, 1993). As such, this final rule was not reviewed by OMB under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

This action does not contain any new or revised information collections subject to OMB approval under the PRA, 44 U.S.C. 3501 *et seq.* Information collection activities contained in the TSCA 8(d) rule are already approved by the Office of Management and Budget (OMB) under OMB Control No. 2070–0004.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq.* The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements under the APA because the Agency has invoked the APA “good cause” exemption.

D. Unfunded Mandates Reform Act (UMRA)

This action will not impose any enforceable duty or contain any unfunded mandate as described under Title II of UMRA, 2 U.S.C. 1531–1538 *et seq.*

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). It 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.

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

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, E.O. 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the Agency has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not a covered regulatory action because it is not “economically significant” under Executive Order 12866 and it does not concern an environmental health risk or safety risk. Although this action would not establish an environmental standard intended to mitigate health or safety risks, the information that would be submitted to EPA in accordance with this rule would be used to inform the Agency’s decision-making process regarding chemical substances to which children may be disproportionately exposed. This information may also assist the Agency and others in determining whether the chemical substances covered in this proposed rule present potential risks, which would allow the Agency and others to take appropriate action to investigate and mitigate those risks.

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

This action is not a “significant energy action” as defined in Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy and has not otherwise been designated by the Administrator of OMB’s Office of Information and Regulatory Affairs as a “significant energy action.”

I. National Technology Transfer and Advancement Act (NTTAA)

Because 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). However, the Agency believes that the information collected through this rule will inform the TSCA risk evaluations that are planned for these chemicals and will thereby enable the Agency to better protect human health and the environment, including in low-income and minority communities.

K. Congressional Review Act (CRA)

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 716

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

Dated: September 23, 2021.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 716—HEALTH AND SAFETY DATA REPORTING

■ 1. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

■ 2. In § 716.120(d), amend the table by revising all the entries under the headings “High-Priority Substances” and “Organohalogen flame retardants” to read as follows:

§ 716.120 Substances and listed mixtures to which this subpart applies.

* * * * *

(d) * * *

Category	CASRN	Special exemptions	Effective date	Sunset date
High-Priority Substances:				
1,3-Butadiene	106-99-0	§ 716.21(a)(9)	7/29/21	12/01/21
Butyl benzyl phthalate (BBP)—1,2-Benzene-dicarboxylic acid, 1-butyl 2(phenylmethyl) ester	85-68-7	§ 716.21(a)(9)	7/29/21	12/01/21
Dibutyl phthalate (DBP) (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester)	84-74-2	§ 716.21(a)(9)	7/29/21	12/01/21
o-Dichlorobenzene	95-50-1	§ 716.21(a)(9)	7/29/21	12/01/21
p-Dichlorobenzene	106-46-7	§ 716.21(a)(9)	7/29/21	12/01/21
1,1-Dichloroethane	75-34-3	§ 716.21(a)(9)	7/29/21	12/01/21
1,2-Dichloroethane	107-06-2	§ 716.21(a)(9)	7/29/21	12/01/21
Trans-1,2-Dichloroethylene	156-60-5	§ 716.21(a)(9)	7/29/21	12/01/21
1,2-Dichloropropane	78-87-5	§ 716.21(a)(9)	7/29/21	12/01/21
Dicyclohexyl phthalate	84-61-7	§ 716.21(a)(9)	7/29/21	12/01/21
Di-ethylhexyl phthalate (DEHP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis(2- ethylhexyl) ester)	117-81-7	§ 716.21(a)(9)	7/29/21	12/01/21
Di-isobutyl phthalate (DIBP)—(1,2-Benzene-dicarboxylic acid, 1,2-bis- (2methylpropyl) ester)	84-69-5	§ 716.21(a)(9)	7/29/21	12/01/21
Ethylene dibromide	106-93-4	§ 716.21(a)(9)	7/29/21	12/01/21
Formaldehyde	50-00-0	§ 716.21(a)(9)	7/29/21	12/01/21
1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB)	1222-05-5	§ 716.21(a)(9)	7/29/21	12/01/21
4,4'-(1-Methylethylidene)bis[2,6-dibromophenol] (TBBPA)	79-94-7	§ 716.21(a)(9)	7/29/21	12/01/21
Phosphoric acid, triphenyl ester (TPP)	115-86-6	§ 716.21(a)(9)	7/29/21	12/01/21
Phthalic anhydride	85-44-9	§ 716.21(a)(9)	7/29/21	12/01/21
1,1,2-Trichloroethane	79-00-5	§ 716.21(a)(9)	7/29/21	12/01/21
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	§ 716.21(a)(9)	7/29/21	12/01/21
Organohalogen flame retardants:				
Bis(2-ethylhexyl) tetrabromophthalate	26040-51-7	§ 716.21(a)(10)	7/29/21	1/25/22
Bis(hexachlorocyclopentadieno) cyclooctane	13560-89-9	§ 716.21(a)(10)	7/29/21	1/25/22
1,2-Bis(2,4,6-tribromophenoxy)ethane	37853-59-1	§ 716.21(a)(10)	7/29/21	1/25/22
1,1'-Ethane-1,2-diylbis(pentabromobenzene)	84852-53-9	§ 716.21(a)(10)	7/29/21	1/25/22
2-Ethylhexyl-2,3,4,5-tetrabromobenzoate	183658-27-7	§ 716.21(a)(10)	7/29/21	1/25/22
2-(2-Hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate	20566-35-2	§ 716.21(a)(10)	7/29/21	1/25/22
2,2'-[(1-Methylethylidene)bis(2,6-dibromo-4,1-phen- ylene)oxymethylene]]bis[oxirane]	3072-84-2	§ 716.21(a)(10)	7/29/21	1/25/22
Mixture of chlorinated linear alkanes C14-17 with 45-52% chlorine	85535-85-9	§ 716.21(a)(10)	7/29/21	1/25/22
N,N-Ethylene-bis(tetrabromophthalimide)	32588-76-4	§ 716.21(a)(10)	7/29/21	1/25/22
Pentabromochlorocyclohexane	87-84-3	§ 716.21(a)(10)	7/29/21	1/25/22
(Pentabromophenyl)methyl acrylate	59447-55-1	§ 716.21(a)(10)	7/29/21	1/25/22
Pentabromotoluene	87-83-2	§ 716.21(a)(10)	7/29/21	1/25/22
Perbromo-1,4-diphenoxybenzene	58965-66-5	§ 716.21(a)(10)	7/29/21	1/25/22
Phosphonic acid, (2-chloroethyl)-, bis(2-chloroethyl) ester	6294-34-4	§ 716.21(a)(10)	7/29/21	1/25/22
Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis(2-chloroethyl) ester	38051-10-4	§ 716.21(a)(10)	7/29/21	1/25/22
Propanoic acid, 2-bromo-, methyl ester	5445-17-0	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A-bis(2,3-dibromopropyl ether)	21850-44-2	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A bis(2-hydroxyethyl) ether	4162-45-2	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A diallyl ether	25327-89-3	§ 716.21(a)(10)	7/29/21	1/25/22
Tetrabromobisphenol A dimethyl ether	37853-61-5	§ 716.21(a)(10)	7/29/21	1/25/22
2,4,6-Tribromoaniline	147-82-0	§ 716.21(a)(10)	7/29/21	1/25/22
1,3,5-Tribromo-2-(prop-2-en-1-yloxy)benzene	3278-89-5	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2-chloroethyl)phosphite	140-08-9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(1-chloro-2-propyl)phosphate	13674-84-5	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2-chloro-1-propyl)phosphate	6145-73-9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(2,3-dibromopropyl)phosphate	126-72-7	§ 716.21(a)(10)	7/29/21	1/25/22
1,3,5-Tris(2,3-dibromopropyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	52434-90-9	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(1,3-dichloro-2-propyl)phosphate	13674-87-8	§ 716.21(a)(10)	7/29/21	1/25/22
Tris(tribromoneopentyl)phosphate	19186-97-1	§ 716.21(a)(10)	7/29/21	1/25/22
2,4,6-Tris-(2,4,6-tribromophenoxy)-1,3,5-triazine	25713-60-4	§ 716.21(a)(10)	7/29/21	1/25/22

[FR Doc. 2021-21164 Filed 9-30-21; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 51c

RIN 0906-AB30

Implementation of Executive Order on Access to Affordable Life-Saving Medications; Rescission of Regulation

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

ACTION: Final rule; rescission of regulations.

SUMMARY: HHS is rescinding the final rule entitled “Implementation of Executive Order on Access to Affordable Life-Saving Medications,” published in the December 23, 2020, *Federal Register* (2020 Rule). HHS is rescinding the 2020 Rule due to the excessive administrative costs and burdens that implementation would have imposed on health centers. In particular, the 2020 Rule required health centers to create and maintain new practices necessary to determine patients’ eligibility to receive certain drugs at or below the discounted price paid by the health center or subgrantees plus a minimal administration fee. HHS finds the 2020 Rule’s implementation would have resulted in reduced resources available to support critical services to health center patients—including those who use insulin and injectable epinephrine. HHS’s consideration of the 2020 Rule’s impact was informed, in part, by the demands on health centers resulting from the COVID-19 pandemic. As Executive Order 13937 remains in effect, HHS is exploring non-regulatory options to implement the Executive Order.

DATES: This rule is effective November 1, 2021.

FOR FURTHER INFORMATION CONTACT: Jennifer Joseph, Director, Office of Policy and Program Development, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857; email: jjoseph@hrsa.gov; telephone: 301-594-4300; fax: 301-594-4997.

SUPPLEMENTARY INFORMATION:

I. Public Participation

On June 16, 2021, HHS published a Notice of Proposed Rulemaking (2021 NPRM) in the *Federal Register* (86 FR 32008) to rescind the “Implementation of Executive Order on Access to

Affordable Life-Saving Medications” rule. The 2021 NPRM provided for a 30-day comment period, and HHS received 332 comments. HHS carefully considered all comments in developing this rule, as outlined in Section VI below, and presents a summary of all significant comments and HHS responses.

II. Background

HHS published the subject NPRM in the *Federal Register* on September 28, 2020 (85 FR 60748), and the 2020 Rule on December 23, 2020 (85 FR 83822). The 2020 Rule established a new requirement directing all health centers receiving grants under section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) that participate in the 340B Program (42 U.S.C. 256b), to the extent that they plan to make insulin and/or injectable epinephrine available to their patients, to provide assurances that they have established practices to provide these drugs at or below the discounted price paid by the health center or subgrantees under the 340B Program (plus a minimal administration fee) to health center patients with low incomes, as determined by the Secretary, who have a high cost sharing requirement for either insulin or injectable epinephrine; have a high unmet deductible; or who have no health insurance.

On June 16, 2021, after a careful reassessment of the comments submitted in response to the proposed rule published at 85 FR 60748 (September 28, 2020) and consideration of the comments received on the proposed rule to delay the effective date published at 86 FR 13872 (March 11, 2021), HHS published the 2021 NPRM to rescind the 2020 Rule. The 2021 NPRM cited significant concerns regarding health centers needing to divert vital resources to implement the 2020 Rule. The 2021 NPRM requested comment on the administrative burden and costs to comply with the 2020 Rule and thus maintain eligibility for future Health Center Program grants. The 2021 NPRM also requested comment on whether a rescission would assist health centers in continuing to provide primary care services to medically underserved and vulnerable populations. HHS noted the administrative burdens associated with the 2020 Rule, particularly in light of health centers’ continuing role in ensuring equitable access to COVID-19 vaccination and maintaining the capacity to provide primary and preventive care that addresses the ongoing and evolving needs of hard-to-reach and disproportionately affected

populations. HHS also noted that the 2020 Rule would carry increased administrative costs and administrative burden and would result in reduced resources being available to support services to health center patients. In addition, most comments submitted previously noted that, in many cases, health centers already voluntarily provided medications at reduced prices to their patients.

The 2021 NPRM comment period ended on July 16, 2021. After review and consideration of all submitted comments, HHS has concluded that the 2020 Rule created excessive administrative burden for health centers, which in turn would have resulted in reduced resources for health center patient services. HHS has determined that the overall impacts of the administrative burden outweigh benefits to patients from the reduction in prices of insulin and injectable epinephrine. Therefore, HHS is issuing this final rule rescinding the 2020 Rule, which was published at 85 FR 83822.

The 2020 Rule became effective on July 20, 2021, prior to publication of this rescission. Due to the timing of Health Center Program funding, grants awarded in Fiscal Year 2022 would be the first opportunity for HRSA to impose the requirements of the “Implementation of Executive Order on Access to Affordable Life-Saving Medications” rule, and so the requirements have not yet been implemented.

III. Statutory Authority

The statement of authority for 42 CFR part 51c cites to sections 330 (42 U.S.C. 254b) and 215 of the Public Health Service Act, (42 U.S.C. 216), respectively.

IV. Overview of This Rule

HHS is rescinding the 2020 Rule and therefore deleting the associated revision to the regulations codified at 42 CFR 51c.303(w). 42 CFR 51c.303(w) stated: “To the extent that an applicant for funding under Section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) has indicated that it plans to distribute, either directly, or through a written agreement, drugs purchased through the 340B Drug Pricing Program (42 U.S.C. 256b), and to the extent that such applicant plans to make insulin and/or injectable epinephrine available to its patients, the applicant shall provide an assurance that it has established practices to provide insulin and injectable epinephrine at or below the discounted price paid by the health center grantee or subgrantee under the 340B Drug Pricing Program (plus a