• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
• Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 31, 2022. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental Protection, Air Pollution Control, Incorporation by Reference, Intergovernmental Relations, Nitrogen Oxides, Ozone, Reporting and Recordkeeping Requirements, Volatile Organic Compounds.

Dated: November 26, 2021.

John Blevins,

Acting Regional Administrator, Region 4.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.2220 amend the table in paragraph (e) by adding, at the end of the table, the entry ''1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area'' to read as follows:

§ 52.2220 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED TENNESSEE NON-REGULATORY PROVISIONS

Name of non-regulatory SIP provision	Applicable geographic or nonattainment area	State effective date	EPA approval date	Explanation
*	*	*	*	*
1997 8-Hour Ozone Second 10-Year Limited Maintenance Plan for the Montgomery County, Tennessee Area.	Montgomery County	6/10/2020	12/2/2021, [Insert citation of publication].	

* * * * *

[FR Doc. 2021–26143 Filed 12–1–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB27

National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table

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

ACTION: Final rule.

SUMMARY: On April 4, 2018, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend the National Vaccine Injury Compensation Program (VICP or Program) Vaccine Injury Table (Table), consistent with the statutory requirement to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant women. Specifically, the Secretary sought public comment regarding how the addition of this new category should be formatted on the Table. Through this final rule, the Secretary amends the Table to add ''and/or pregnant women'' after ''children'' to the existing language in Item XVII as proposed in the NPRM. This change will apply only to petitions for compensation under the VICP filed after the effective date of this final rule.

DATES: This rule is effective January 3, 2022.

FOR FURTHER INFORMATION CONTACT: Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, 5600 Fishers Lane, Room 8N146B, Rockville, MD 20857, or by telephone (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Background

The National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660 (42 U.S.C. 300aa-10 *et seq.*), established the VICP, a Federal compensation program for individuals thought to be injured by certain vaccines. The statute governing the VICP has been amended several times since 1986 and will be hereinafter

referred to as ''the Vaccine Act.'' Petitions for compensation under the VICP are filed in the United States Court of Federal Claims (Court), with a copy served on the Secretary, who is the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes findings as to eligibility for, and the amount of, compensation.

To gain entitlement to compensation under this Program, a petitioner must establish that a vaccine-related injury or death has occurred, either by proving that a vaccine actually caused or significantly aggravated an injury (causation-in-fact) or by demonstrating the occurrence of what is referred to as a ''Table injury.'' That is, a petitioner may show that the vaccine recipient suffered an injury of the type enumerated in the regulations at 42 CFR 100.3—the ''Vaccine Injury Table''—corresponding to the vaccination in question and that the onset of such injury took place within the period also specified in the Table. If so, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other Vaccine Act requirements are satisfied) unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination (see 42 U.S.C. 300aa–11(c)(1)(C)(i), 300aa–13(a)(1)(B), and 300aa–14(a)).

Revisions to the Table are authorized under 42 U.S.C. 300aa–14(c) and (e). Prior to the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), the only vaccines covered under the VICP were those recommended by the CDC for routine administration to children (for example, vaccines that protect against seasonal influenza), are subject to an excise tax by Federal law, and added to the Table by the Secretary. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as their corresponding illness, disability, injury, or condition covered, and the requisite time within which the first symptom or manifestation of onset or significant aggravation must begin after the vaccine administration to receive the Table's legal presumption of causation. One category of the Table, ''Item XVII,'' includes, ''Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children, after publication by the Secretary of a notice of coverage.'' Two injuries—Shoulder Injury Related to Vaccine Administration (SIRVA) and vasovagal syncope—are listed as associated injuries for this category. Through this general category, new vaccines recommended by the CDC for routine administration to children and subject to an excise tax are covered under the VICP prior to being added to the Table as a separate vaccine category.

The Cures Act amended 42 U.S.C. 300aa–14(e) to expand the types of vaccines covered under the VICP. *See* section 3093(c)(1) of the Cures Act. The amended statute requires that the Secretary revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). *See* 42 U.S.C. 300aa–14(e)(3). This action does not alter the current status quo because the CDC has not recommended any categories of vaccines for routine administration to pregnant women that are not also recommended for routine administration to children.

Summary of the Final Rule

As discussed in the NPRM (83 FR 14391), Congress enacted a mechanism for modification of the Table, through the promulgation of regulatory changes by the Secretary after consultation with the Advisory Commission on Childhood Vaccines (ACCV). The Secretary is revising the Table to include new vaccines recommended by the CDC for routine administration in pregnant women in Item XVII of the Table. On September 8, 2017, the Program consulted the ACCV regarding options for adding this new category of vaccines to the Table. The ACCV voted unanimously to amend the existing language in Item XVII of the Table to add ''and/or pregnant women'' after ''children'' authorizing coverage under the VICP of any new vaccine recommended by CDC for routine administration in pregnant women (and subject to an excise tax) after the publication of a notice of coverage. The ACCV viewed this option as a simple approach to revising the Table, rather than adding a new general Item XVIII to the Table for vaccines recommended for routine administration in pregnant women. Therefore, following the ACCV's recommendation, the Secretary has amended the existing language in Item XVII of the Table to add ''and/or pregnant women'' after ''children.'' This amendment allows any new vaccine recommended by the CDC for routine administration in pregnant women (and subject to an excise tax) to be added to this general category of the Table after the Secretary publishes a notice of coverage. The publication of a notice of coverage reflects the Secretary's approval of CDC's recommendation and the determination that the statutory requirements for coverage under the VICP have been met.

The Secretary also has retained the two injuries currently associated with Item XVII of the Table, SIRVA and vasovagal syncope, as Table injuries for vaccines recommended by the CDC for routine administration in pregnant women. In its 2012 Report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any new injected vaccines that potentially may lead to SIRVA or vasovagal syncope. Therefore, the Secretary also has included these injuries on the Table for new vaccines recommended by the CDC for routine administration in pregnant women.

VICP petitions must be filed within the applicable statutes of limitations. With the Table change, the general statutes of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa–16(a), continue to apply. The alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) does not apply to this Table change. This is because, at present, there are no vaccines added to the Table under the revised general category, since the only vaccines the CDC currently recommends for routine administration in pregnant women are already covered on the Table. In the future, when any new vaccine, not already covered under the VICP, is recommended by the CDC for routine administration in pregnant women, subject to an excise tax, and added to the Table, the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) would apply if certain requirements are met.[1]

II. Responses to Public Comments

The NPRM provided a 180-day comment period (April 4, 2018–October 1, 2018), and HRSA received 51 comments during that time, including during a public hearing. There were 48 written comments submitted. The

[1] Under 42 U.S.C. 300aa–16(b), the alternate statute of limitations applies where the effect of the revision would make an individual, who was not eligible before the revision, eligible to seek compensation under the Program or to significantly increase the individual's likelihood of obtaining compensation.

number and sources of the comments are as follows: 44 from individuals, two from pharmaceutical companies, and two from organizations, with one stating it represents 12 other entities. In addition, HRSA held a public hearing on the NPRM on September 17, 2018, and a national organization and two individuals presented oral comments.

While the Secretary only sought public comment on how best to implement the statutory amendment to add vaccines recommended by the CDC for routine administration in pregnant women to the Table, many commenters offered comments beyond the scope of the request. Nevertheless, the Secretary carefully considered all 51 comments received in the development of this final rule. Below is a summary of the comments and the Secretary's response to them.

Comment: Several comments supported the addition of vaccines recommended for routine administration in pregnant women to the Table, stating that maternal immunization will improve the health of the mother, her unborn child, newborns, and the overall health of the nation.

Response: Based on existing evidence and data trends, the Secretary agrees that the eradication and reduction of vaccine-preventable diseases through immunization has directly increased life expectancy by reducing mortality. Pregnant women are at risk for vaccine-preventable disease–related morbidity and mortality and adverse pregnancy outcomes, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight. In addition to providing direct maternal benefit, vaccination during pregnancy likely provides direct fetal and infant benefit through passive immunity (transplacental transfer of maternal vaccine-induced antibodies). Among the vaccines recommended by the CDC for adults, currently, two are specifically recommended for routine administration during pregnancy, and hepatitis A, hepatitis B, meningococcal (ACWY), and meningococcal (B) are recommended in pregnancy based on additional risk factors.

Comment: A comment supporting the proposed changes in the NPRM suggests that the recommendations of the CDC should be included as additional language on the Table, supporting the safe administration of vaccines in pregnant women.

Response: The Table does not include language about the safe administration of vaccines, as the purpose of the Table is to list and explain injuries and/or conditions that are presumed to be caused by covered vaccines, unless another cause is proven, for potential compensation under the VICP. However, CDC develops best practice guidance for the safe administration of vaccines that can be found at *https://www.cdc.gov/vaccines/hcp/acip-recs/index.html.*

Comment: Comments supporting the proposed changes in the NPRM indicated that the CDC recommendations for the administration of routine vaccination to pregnant women would result in increased communication and knowledge around vaccines recommended for pregnant women, leading to increased informed consent and facilitate decision-making regarding immunizations. In addition, this may result in the development of new vaccines for pregnant women.

Response: Recommendations for the routine use of vaccines in pregnant women are issued by the CDC and are harmonized to the greatest extent possible with recommendations made by the American College of Gynecologists and Obstetricians, the American Academy of Family Physicians, and the American College of Physicians. The Advisory Committee on Immunization Practices, established in 1964 by the Surgeon General of the United States, is chartered as a Federal advisory committee to provide expert external advice and guidance to the Director of the CDC on the use of vaccines in the civilian population. The Advisory Committee on Immunization Practices makes recommendations to the Director of the CDC for vaccines authorized or licensed by the Food and Drug Administration for the prevention of diseases. Providing information regarding whether these recommendations increase communication and knowledge around vaccines recommended for pregnant women, and facilitating decision-making regarding immunizations, is beyond the scope of this final rule.

Comment: Some comments supporting the proposed changes in the NPRM suggested that adding the category of pregnant women to the Table would allow the VICP to function more efficiently and pregnant women would have recourse should an alleged injury occur.

Response: The Secretary agrees that the addition of the category of vaccines recommended for routine administration in pregnant women to the Table will make the VICP function more efficiently. The addition of such vaccines to Item XVII of the Table will allow any new vaccines that in the future are recommended by the CDC for routine administration in pregnant women (and subject to an excise tax) to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking.

In addition, the Table lists covered vaccines and associated injuries, making it easier for some people to get compensation. The Table lists and explains injuries and/or conditions that are presumed to be caused by vaccines unless another cause is proven. The Table's Qualification and Aids to Interpretation define some of the injuries and/or conditions listed on the Table. The Table also lists periods in which the first symptom of these injuries and/or conditions must occur after receiving the vaccine to receive the Table's presumption of causation. If the first symptom of an injury and/or condition listed on the Table occurs within the listed time, and any associated definition(s) included in the Qualification and Aids to Interpretation are satisfied, it is presumed that the vaccine was the cause of the injury or condition unless another cause is proven.

Comment: Several comments opposed the proposed changes in the NPRM because they stated that the administration of vaccines to pregnant women and their unborn children causes injuries, such as miscarriages, pre-eclampsia, cancer, autism, neurodevelopmental disorders of infants, and learning disabilities. Some opposed the addition of the category of pregnant women to the Table because they believe that there is a lack of vaccine safety testing and studies, especially regarding the administration of vaccines in pregnant women. Some comments suggested there is no scientific evidence that vaccinating pregnant women is safe or advantageous and that there are limited benefits and increased risks for vaccinating pregnant women. In addition, some adamantly opposed all vaccinations.

Response: As noted in the NPRM, a recent amendment to the Vaccine Act requires that the Secretary revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). See 42 U.S.C. 300aa–14(e)(3).

Moreover, the United States has a long-standing vaccine safety program that closely and constantly monitors the safety of vaccines. A critical part of the vaccine safety program is the CDC's Immunization Safety Office, which identifies possible vaccine side effects and conducts studies to determine whether health problems are caused by vaccines. Information regarding vaccine

safety and current research are available by conducting literature reviews.

Pregnant women are at risk for vaccine-preventable disease-related morbidity and mortality and adverse pregnancy outcomes, including congenital anomalies, spontaneous abortion, preterm birth, and low birth weight. In addition to providing direct maternal benefit, vaccination during pregnancy may provide direct fetal and infant benefit through passive immunity (transplacental transfer of maternal vaccine-induced antibodies).

Existing evidence and data trends indicate that the eradication and reduction of vaccine-preventable diseases through immunization has directly increased life expectancy by reducing mortality. In addition, numerous published and peer-reviewed scientific studies have found that neither vaccines nor vaccine ingredients cause the neurodevelopmental disorders of autism, Attention-Deficit/Hyperactivity Disorder, or speech or language delay.

Comment: Some comments opposing the proposed changes in the NPRM stated that pregnant women are often coerced or forced to be vaccinated without being given information about possible vaccine side effects to themselves and/or their unborn child/children.

Response: This final rule does not require vaccines for pregnant women. However, the CDC and the American Academy of Pediatrics, as well as other medical organizations, publish information regarding the safety of recommended vaccines. In addition, Vaccine Information Statements, which are information sheets produced by the CDC that explain both the benefits and risks of VICP-covered vaccines, are required to be provided to all individuals, or their legal representatives, before receiving such vaccines. However, the decision to ultimately be vaccinated rests with the individual or legal representative.

Comment: Some comments opposing the NPRM stated that by recommending vaccines to pregnant women, liability protection is conferred upon vaccine manufacturers and that this creates a disincentive to conduct safety research on vaccines. Some stated a belief that the addition of pregnant women will now eliminate the pregnant woman's right to sue for damages.

Response: The Vaccine Act created the VICP, a no-fault alternative to the traditional tort system. It provides compensation to people thought to be injured by vaccines recommended by the CDC for routine administration to children and now pregnant women. When a vaccine is added to the Vaccine Injury Table, it is covered under the VICP. To help ensure a stable vaccine supply, the VICP generally provides liability protection for vaccine manufacturers and health care providers for injuries caused by VICP-covered vaccines. Claims alleging injuries or death from certain vaccines generally must be filed with the VICP before a lawsuit can be filed in civil court.

Comment: Some comments opposed the addition of the category of vaccines recommended for routine administration in pregnant women to the Table, as this would provide vaccine manufacturers the ability to increase revenue by having a new population to target with their products.

Response: As noted previously, the Secretary is required by statute to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). See 42 U.S.C. 300aa–14(e)(3).

Comment: Some comments opposing the change proposed in the NPRM suggested that the VICP be eliminated.

Response: The Vaccine Act established the VICP, and Congress would need to enact legislation to eliminate the VICP. Eliminating the Program is beyond the scope of this final rule.

Comment: Some comments supporting and opposing the changes proposed in the NPRM suggested additional changes to the Table, such as adding injuries to the Table. Commenters opposing changes proposed in the rule stated that vaccines cause miscarriages and other conditions, such as chorioamnionitis, encephalitis/encephalopathy, Guillain-Barré Syndrome, and neurodevelopmental disorders, and can negatively affect the offspring of pregnant women who have undiagnosed genetic disorders. Some commenters requested that the Table be revised or expanded to include all vaccines that could be recommended in pregnancy and their potential complications, and vaccines contraindicated during pregnancy, including statistics of complications.

Response: Consistent with the statutory requirement, the Secretary is revising the Table to include new vaccines recommended by the CDC for routine administration in pregnant women. The Secretary is implementing this change by amending the existing language in Item XVII of the Table to include ''and/or pregnant women'' after ''children.'' This will add to that general category of the Table, any new vaccine recommended by the CDC for routine administration in pregnant women, after imposition of an excise tax and publication of a notice of coverage by the Secretary.

As explained above, in its 2012 Report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the Institute of Medicine considered SIRVA and vasovagal syncope as mechanistic injuries resulting from the injection of a vaccine and not from the contents of a particular formulation of a vaccine. Thus, these conditions are listed as Table injuries for any new vaccine recommended by the CDC for routine administration to children or pregnant women (after the imposition of an excise tax and publication by the Secretary of a notice of coverage) to account for any new injected vaccines that potentially may lead to SIRVA or vasovagal syncope. In the future, when specific vaccines recommended for routine administration in pregnant women are added to the Table, the Secretary will review the literature to determine if other injuries should be added to the Table for those new vaccines.

Comment: Comments supporting and opposing the proposed change in the NPRM speculated that there is the potential for increased compensation for adverse reactions resulting from increased injury claims, as both the mother and her unborn child are now eligible to file a claim for a vaccine related injury. Commenters expressed concern with possible abuse in reporting and compensation, compounded by the addition of SIRVA and vasovagal syncope as injuries to the Table.

Response: The Secretary is required by statute to revise the Table to include vaccines recommended by the CDC for routine administration in pregnant women (and subject to an excise tax by Federal law). *See* 42 U.S.C. 300aa–14(e)(3). Additionally, with respect to vaccination of pregnant women, the Cures Act permits two VICP petitions to be filed: One on behalf of a woman who was pregnant when vaccinated and one on behalf of her live-born child whose injury(s) was allegedly sustained *in utero. See* 42 U.S.C. 300aa–11(b)(2).

Comment: A commenter questioned who would be the proper petitioner in the context of maternal immunization (*i.e.,* would the petitioner be the pregnant woman, the child born after his/her pregnant mother was vaccinated, or both?).

Response: The Cures Act amended the Vaccine Act to permit VICP claims filed on behalf of live-born children for injuries allegedly sustained *in utero* as a result of maternal immunizations with respect to covered vaccines. *See* 42

U.S.C. 300aa–11(f). In addition, the Cures Act modified the Vaccine Act's ''one petition'' requirement by allowing two VICP petitions: One on behalf of a woman who was pregnant when vaccinated and one on behalf of her child whose injury(s) was allegedly sustained *in utero. See* 42 U.S.C. 300aa–11(b)(2).

III. Regulatory Impact Analysis

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when rulemaking is necessary, to select regulatory approaches that provide the greatest net benefits (including potential economic, environmental, public health, safety, distributive, and equity effects). In addition, under the Regulatory Flexibility Act, if a rule has a significant economic effect on a substantial number of small entities, HHS must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

The Office of Information and Regulatory Affairs has determined that this rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866.

HHS has determined that no substantial additional administrative and compensation resources are required to implement the requirements in this rule. Compensation will be made in the same manner. As in all other VICP cases, to be found entitled to compensation, petitioners will need to prove by a preponderance of the evidence either that they meet the requirements of the Table or that their injury was caused by the vaccine unless the respondent affirmatively shows that the injury was caused by some factor other than the vaccination. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The National Vaccine Injury Compensation Program: Adding the Category of Vaccines Recommended for Pregnant Women to the Vaccine Injury Table Final Rule is ''not significant'' because no substantial resources are required to implement the requirements in this rule. This rule adds ''and/or pregnant women'' to the new vaccines category (Item XVII) on the Table. Currently, the only vaccines recommended for routine administration in pregnant women are already on the Table because they are recommended for routine administration to children and have an excise tax imposed on them. Therefore, this final rule does not have a significant impact on a substantial number of small entities. Additionally, this rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. We have determined that the final rule is not a ''major rule'' within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on state, local, and tribal governments and on the private sector such as requiring consultation under the Unfunded Mandates Reform Act of 1995.

The provisions of this final rule do not, on the basis of family well-being, affect the following family elements: Family safety; family stability; marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning; disposable income or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999.

This final rule is not being treated as a ''significant regulatory action'' as defined under section 3(f) of Executive Order 12866. As stated above, this final rule will modify the Table based on legal authority.

Impact of the New Rule

This final rule will allow any vaccines that in the future are recommended by the CDC for routine administration to pregnant women and subject to an excise tax to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking. In addition, this final rule will have the effect of making it easier for future petitioners alleging injuries that meet the criteria in the Vaccine Injury Table to receive the Table's presumption of causation, which relieves them of having to prove that the vaccine actually caused or significantly aggravated their injury.

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Accordingly, 42 CFR part 100 is amended as set forth below:

PART 100—VACCINE INJURY COMPENSATION

■ 1. The authority citation for 42 CFR part 100 continues to read as follows:

Authority: Secs. 312 and 313 of Public Law 99–660 (42 U.S.C. 300aa–1 note); 42 U.S.C. 300aa–10 to 300aa–34; 26 U.S.C. 4132(a); and sec. 13632(a)(3) of Public Law 103–66.

■ 2. In § 100.3, amend the Table in paragraph (a) by revising entry ''XVII'' to read as follows:

§ 100.3 Vaccine injury table.

(a) * * *

VACCINE INJURY TABLE

Vaccine	Illness, disability, injury, or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
* * * *	* * *	
XVII. Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women, after publication by the Secretary of a notice of coverage.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.

* * * * *

[FR Doc. 2021–26197 Filed 12–1–21; 8:45 am]

BILLING CODE 4150–28–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 63

[IB Docket No. 16–155; FCC 21–104]

Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership

AGENCY: Federal Communications Commission.

ACTION: Final action.

SUMMARY: This document summarizes the Federal Communications Commission's (Commission) decision in the Second Report and Order in the *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership* proceeding, in which the Commission adopted Standard Questions that certain applicants with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications.

DATES: The Commission adopted the Standard Questions on September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Jocelyn Jezierny, International Bureau, Telecommunications and Analysis Division, at (202) 418–0887 or *Jocelyn.Jezierny@fcc.gov.* For information regarding the PRA information collection requirements contained in the PRA, contact Cathy Williams, Office of the Managing Director, at (202) 418–2918 or *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order, FCC 21–104, adopted on September 30, 2021, and released on October 1, 2021. The full text of this document is available on the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-21-104A1.pdf.* To request materials in accessible formats for people with disabilities, send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Supplemental Final Regulatory Flexibility Analysis

As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared a Supplemental Final Regulatory Flexibility Analysis (Supplemental FRFA) of the possible significant impact on small entities of the Standard Questions and procedures addressed in this Second Report and Order.

Congressional Review Act

The Commission will include a copy of this Second Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A).

Synopsis

I. Introduction

1. In this Second Report and Order, we adopt a set of standardized national security and law enforcement questions (Standard Questions) that certain applicants and petitioners (together, ''applicants'') with reportable foreign ownership will be required to answer as part of the Executive Branch review process of their applications and petitions (together, ''applications''). In the *Executive Branch Review Order,* the Commission adopted rules and procedures to facilitate a more streamlined and transparent review process for coordinating applications with the Executive Branch agencies (the Departments of Justice, Homeland Security, Defense, State, and Commerce, as well as the United States Trade Representative) for their views on any national security, law enforcement, foreign policy, or trade policy issues associated with the foreign ownership of the applicants. The *Executive Branch Review Order* also established firm time frames for the Executive Branch agencies to complete their review consistent with Executive Order 13913, which established the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector (the Committee).[1] To expedite the national security and law enforcement review of such applications, applicants must provide their answers to the Standard Questions directly to the Committee prior to or at the same time they file their applications with the Commission. This process would replace the current practice of the Executive Branch seeking such threshold information directly from the applicants after the Commission refers the applications.

II. Background

2. For over 20 years, the Commission has referred certain applications that have reportable foreign ownership to the Executive Branch agencies for their review.[2] In the *Executive Branch Review Order,* the Commission formalized the review process and established firm time frames for the Executive Branch national security and law enforcement agencies to complete their review, consistent with Executive Order 13913 that established the Committee in 2020. The types of applications the Commission generally refers include applications for international section 214 authorizations and submarine cable landing licenses and applications to assign, transfer control or modify such authorizations and licenses where the applicant has reportable foreign ownership, and all petitions for section 310(b) foreign ownership rulings.[3]

[1] Executive Order No. 13913 of April 4, 2020, Establishing the Committee for the Assessment of Foreign Participation in the United States Telecommunications Services Sector, 85 FR 19643, 19643 through 44 (Apr. 8, 2020) (Executive Order 13913) (establishing the ''Committee,'' composed of the Secretary of Defense, the Secretary of Homeland Security, and the Attorney General of the Department of Justice, who serves as the Chair, and the head of another executive department or agency, or any Assistant to the President, as the President determines appropriate (Members), and also providing for Advisors, including the Secretary of State, the Secretary of Commerce, and the United States Trade Representative); *id.* (stating that, ''[t]he security, integrity, and availability of United States telecommunications networks are vital to United States national security and law enforcement interests'').

[2] In adopting rules for foreign carrier entry into the U.S. telecommunications market over two decades ago in its *Foreign Participation Order,* the Commission affirmed that it would consider national security, law enforcement, foreign policy, and trade policy concerns in its public interest review of applications for international section 214 authorizations and submarine cable landing licenses and petitions for declaratory ruling under section 310(b) of the Act. *Rules and Policies on Foreign Participation in the U.S. Telecommunications Market; Market Entry and Regulation of Foreign-Affiliated Entities,* IB Docket Nos. 97–142 and 95–22, Report and Order and Order on Reconsideration, 12 FCC Rcd 23891, 23919, paragraph 63 (1997) (*Foreign Participation Order*), recon. denied, 15 FCC Rcd 18158 (2000).

[3] *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership,* IB Docket No. 16–155, Report and Order, 85 FR 76360 (Nov. 27, 2020), 35 FCC Rcd 10927, 10935–38, paragraphs 24 through 28 (2020) (*Executive Branch Review Order*) (setting out which types of applications will generally be referred to the Executive Branch, but noting the Commission has the discretion to refer additional types of applications if we find that the specific circumstances of an application require the input of the Executive Branch); *see also Erratum* (Appendix B—Final Rules), DA 20–1404 (OMD/IB rel. Nov. 27, 2020), 47 CFR 1.40001(a)(1); *Numbering Policies for Modern Communications,* WC Docket No. 13–97; *Telephone Number Requirements for IP-Enabled Service Providers,* WC Docket No. 07–243; *Implementation of TRACED Act Section 6(a)—Knowledge of Customers by Entities with Access to Numbering Resources,* WC Docket No. 20–67; *Process Reform for Executive Branch Review of Certain FCC Applications and Petitions Involving Foreign Ownership,* IB Docket No. 16–155, Further Notice of Proposed Rulemaking, FCC 21 through 94, paragraphs 23 through 29 (2021) (seeking comment on referring certain numbering applications to the