hearings prior to adoption and submittal of this rule, in accordance with the requirements of CAA sections 110(a)(2) and 110(l).

We are also approving Rules 130, 220, and 230 because we have determined these rules satisfy all of the statutory and regulatory requirements for an NSR permit program (including the PSD program) as set forth in the applicable provisions of part C of title I of the Act and in 40 CFR 51.165 and 40 CFR 51.307. The revisions to these rules also resolve the limited disapproval issues from the October 2016 action.

Our TSD, which can be found in the docket for this rule, contains a more detailed discussion of the approval criteria.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until May 4, 2018. If we take final action to approve the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the NSCAPCD rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through www.regulations.gov and at the EPA Region IX Office (please contact the person identified in the FOR FURTHER INFORMATION CONTACT section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA’s role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; 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).

In addition, 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 and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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. Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 4, 2018. 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, New Source Review, Particulate matter, Reporting and recordkeeping requirements.

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

Dated: March 26, 2018.

Deborah Jordan,
Acting Regional Administrator, Region IX.
[FR Doc. 2018–06878 Filed 4–3–18; 8:45 am]
BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB14

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), HHS.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: As required by a recent amendment to the VICP’s authorizing statute, the Secretary of the Department of Health and Human Services (Secretary) proposes to amend the National Vaccine Injury Compensation Program (VICP) Vaccine Injury Table (Table) to include vaccines recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in pregnant
women. Thus, the Secretary is only seeking public comment on how the addition of this new category is proposed to be formatted on the Table.

DATES: Written comments must be submitted on or before October 1, 2018.

ADDRESSES: You may submit comments, identified by the Regulatory Information Number (RIN) 0906–AB14 in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only one of these ways to minimize the receipt of duplicate submissions.

1. Federal eRulemaking Portal. You may submit comments electronically to http://www.regulations.gov. Click on the link “Submit electronic comments” on HRSA regulations with an open comment period. You may submit attachments to comments in any file format accepted by Regulations.gov.

2. Regular, express, or overnight mail. You may mail written comments to the following address only: Health Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. Delivery by hand (in person or by courier). If you prefer, you may deliver your written comments before the close of the comment period to the same address, 5600 Fishers Lane, Room 13N82, Rockville, MD 20857. Please call one of our HRSA Regulations Office staff members at telephone number (301) 443–1785 in advance to schedule your arrival. This is a toll-free number.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, the program cannot accept comments by facsimile (FAX) transmission. When commenting, by any of the above methods, please refer to file code (#HRSA–0906–AB14). Comments received on a timely basis will be available for public inspection online at www.regulations.gov or in person at the Health Resources and Services Administration’s offices, 5600 Fishers Lane, Room 13N82, Rockville, MD, Monday through Friday of each week from 8:30 a.m. to 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Please visit the National Vaccine Injury Compensation Program’s website, http://www.hrsa.gov/vaccine-compensation/, or contact Dr. Narayan Nair, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 08N146B, Rockville, MD 20857. Phone calls can be directed to (855) 266–2427. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) urges all interested parties to examine this regulatory proposal carefully and to share your views with us, including any supporting data. We must consider all relevant written comments received during the comment period before issuing a final rule. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

If you are a person with a disability and/or a user of assistive technology who has difficulty accessing this document, please see the “For Further Information” box above for the names and contact information to obtain this information in an accessible format. Please visit http://www.HHS.gov/ regulations for more information on HHS rulemaking and opportunities to comment on proposed and existing rules.

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 as a no-fault alternative to the traditional legal system for resolving vaccine injury petitions and to provide compensation for individuals thought to be injured by certain vaccines. Congress has amended the statute governing the VICP several times since 1986. Petitions for compensation under this Program 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 be entitled to an award under the VICP, a petitioner must establish a vaccine-related injury or death, 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 received a covered vaccine and suffered an injury of the type listed for that vaccine in the regulations at 42 CFR 100.3—the Table—and that the onset of such injury took place within the time period specified in the Table. If these criteria are met, the injury is presumed to have been caused by the vaccination, and the petitioner is entitled to compensation (assuming that other 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). Currently, cases are often resolved by negotiated settlements between the parties and approved by the Court. In negotiated settlements, HHS and the Court have not concluded, based upon review of the evidence, that the vaccine caused the alleged injury.

Revisions to the Table are authorized under subsections 2114(c) and (e) of the Public Health Service (PHS) Act (42 U.S.C. 300aa–14(c) and (e)). Prior to the 21st Century Cures Act (Pub. L. 114–255), the only vaccines covered under the VICP were those recommended for routine administration to children by the CDC (for example, vaccines that protect against seasonal influenza), subject to an excise tax by Federal law, and added to the Program by the Secretary. The Table currently includes 17 vaccine categories, with 16 categories for specific vaccines, as well as the corresponding illness, disability, injury, or condition covered; and the requisite time period when the first symptom or manifestation of onset or of significant aggravation after the vaccine administration must begin to receive the VICP’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 through Federal rulemaking.

The 21st Century Cures Act amended section 2114(e) of the PHS Act (42 U.S.C. 300aa–14(e)) to expand the types of vaccines covered under the VICP. See section 3009(c)(1) of the 21st Century Cures Act. The revised 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 section 2114(e)(3) of the PHS Act (42 U.S.C. 300aa–14(e)(3)). Currently, the CDC recommends only two vaccines for routine administration in pregnant women: (1) The tetanus, diphtheria, and...
acellular pertussis vaccine,1 and (2) the seasonal influenza vaccine.2 These categories of vaccines are already covered under the VICP, as the CDC recommends them for routine administration to children and they are subject to an excise tax.

**Discussion of Proposed Table Changes**

Congress enacted a mechanism for modification of the statutory Table, through the promulgation of regulatory changes by the Secretary, after consultation with the Advisory Commission on Childhood Vaccines (ACCV). As required by statute, the Secretary is proposing to revise the Table to include new vaccines recommended by the CDC for routine administration in pregnant women, and seeks comment on the means of effectuating this revision. The Secretary also proposes retaining 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 newly developed injected vaccines that potentially may lead to SIRVA or syncope. Therefore, the Secretary proposes including these injuries on the Table for new vaccines recommended by the CDC for routine administration in pregnant women.

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 include “and/or pregnant women” after “children” permitting coverage under the VICP of any new vaccine recommended by CDC for routine administration in pregnant women and subject to an excise tax after publication by the Secretary of a notice of coverage. They viewed this option as a simple approach to revising the Table, rather than adding a new general Item XVII to the Table for vaccines recommended for routine administration in pregnant women. Therefore, the Secretary is proposing to amend the existing language in Item XVII of the Table to include “and/or pregnant women” after “children” in accordance with the ACCV’s recommendation which would 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.

HHS seeks comments regarding the proposed method of revising the Table, that is, to amend the existing language in Item XVII to include “and/or pregnant women” after “children” which would 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. HHS notes that an important consideration in proposing changes to the Table is the clarity of such changes.

Petitions must be filed within the applicable statute of limitations. With the proposed change, the general statute of limitations applicable to petitions filed with the VICP, set forth in 42 U.S.C. 300aa–16(a) continue to apply. Specifically, in the case of an injury, the claim must be filed within 36 months after the first symptoms appeared. In the case of a death, the claim must be filed within 24 months of the death and within 48 months after the onset of the vaccine-related injury from which the death occurred.

In addition, 42 U.S.C. 300aa–16(b) allows petitioners an alternative statute of limitations of 2 years from the date of the Table change for injuries or deaths that occurred up to 8 years before the Table change if the revision makes a petitioner eligible to seek compensation or significantly increases the likelihood of a petitioner obtaining compensation. However, the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) is not applicable at this time for this proposed Table change. At present, there are no vaccines to add to the Table under the revised general category because the only vaccines the CDC recommends for routine administration in pregnant women are already covered on the Table—(1) Diphtheria, tetanus, and pertussis vaccine and (2) the seasonal influenza vaccine—because they are also recommended by the CDC for routine administration to children, are subject to an excise tax. However, 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 (and/or any additional associated injury), the alternate statute of limitations afforded by 42 U.S.C. 300aa–16(b) would apply, if the effect of the revision would be to 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.

Based on the requirements of the Administrative Procedure Act, HHS publishes an NPRM in the Federal Register before a regulation is promulgated. The public is invited to submit comments on this proposed rule. HHS specifically requests the public’s views on the proposed option for adding new vaccines recommended by the CDC for routine administration in pregnant women to the Table. In addition, a public hearing will be held for this proposed rule. After the 180-day public comment period has ended, the comments received and HHS’s responses to the comments will be addressed in the preamble of the final rule. HHS will publish the final rule in the Federal Register.

**Additional VICP Provisions in the 21st Century Cures Act**

While not seeking comment on these changes in response to this NPRM, the Secretary notes that the 21st Century Cures Act included additional amendments to the Vaccine Act. The 21st Century Cures Act also amended section 2111 of the PHS Act (42 U.S.C. 300aa–11) to permit both a woman who received a covered vaccine while pregnant and any live-born child who was in utero at the time such woman received the vaccine to be considered persons to whom the covered vaccine was administered. See section 3093(c)(2) of the 21st Century Cures Act, adding 42 U.S.C. 300aa–11(f). The amendments to this section also provide that a covered vaccine administered to a pregnant woman constitutes more than one vaccine administration—one to the mother and one to each live-born child who was in utero at the time such woman was administered the vaccine. See section 3093(c)(3) of the 21st Century Cures Act, amending 42 U.S.C. 300aa–11(b)(2). These provisions do not require regulatory actions to implement.

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Economic and Regulatory Impact

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (September 19, 1980), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act, and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). As discussed below, HHS estimates that this proposed rulemaking is not “economically significant” as measured by the $100 million threshold, and hence not a major rule under the Congressional Review Act.

The Secretary has determined that no substantial additional administrative and compensation resources are required to implement the requirements in this proposed 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 actually 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 Notice of Proposed Rulemaking 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: (1) The tetanus, diphtheria, and acellular pertussis vaccine; and (2) the seasonal influenza vaccine. These vaccines are already on the Table because they are recommended for routine administration to children and have an excise tax imposed on them. Therefore, this 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 to require consultation under the Unfunded Mandates Reform Act of 1995.

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

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017. It has been determined that this proposed rule is not significant and thus is exempt from regulatory or deregulatory action for the purposes of Executive Order 13771.

Impact of the New Rule

This proposed rule will allow any new vaccines that in the future are recommended by the CDC for routine administration in pregnant women and subject to a Federal excise tax to be covered under the VICP after the Secretary issues a notice of coverage, without requiring further rulemaking. In addition, this proposed 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 proposed rule has no information collection requirements.

Dated: March 16, 2018.

George Sigounas,
Administrator, Health Resources and Services Administration.


Alex M. Azar II,
Secretary, Department of Health and Human Services.

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

PART 100—VACCINE INJURY COMPENSATION

§ 100.3 Vaccine injury table.

(a) * * *
Synopsis

1. Background. Section 7, entitled “New Technologies and Services,” reads in its entirety as follows:
   (a) It shall be the policy of the United States to encourage the provision of new technologies and services to the public. Any person or party (other than the Commission) who opposes a new technology or service proposed to be permitted under this Act shall have the burden to demonstrate that such proposal is inconsistent with the public interest.
   (b) The Commission shall determine whether any new technology or service proposed in a petition or application is in the public interest within one year after such petition or application is filed. If the Commission initiates its own proceeding for a new technology or service, such proceeding shall be completed within 12 months after it is initiated.

2. Discussion. In this NPRM, the Commission proposes to adopt rules describing guidelines and procedures to implement the stated policy goal of section 7 “to encourage the provision of new technologies and services to the public.” Although the forces of competition and technological growth work together to enable the development and deployment of many new technologies and services to the public, the Commission has at times been slow to identify and take action to ensure that important new technologies or services are made available as quickly as possible. The Commission has sought to overcome these impediments by streamlining many of its processes, but all too often regulatory delays can adversely impact newly proposed technologies or services.

3. Section 7 reflects clear Congressional intent to encourage and expedite provision of technological innovation that would serve the public interest. To better align purpose and practice, the Commission propose a set of rules that will allow the Commission to effectively breathe life into section 7.

4. By its terms, §7 could apply to any petition or application that includes a proposal involving the use of new technologies and services. Accordingly, the Commission proposes to interpret §7 to include petitions for rulemaking or waiver of the Commission’s rules as well as applications for authorization of any type of technology or service within the Commission’s statutory purview, whether radio-based, wired, or otherwise. The Commission also proposes to interpret §7 to apply to any petitions or applications that properly could be resolved either by the Commission or by any Bureau or Office pursuant to delegated authority. Whether the Commission itself, or a particular Bureau or Office acting on delegated authority, would address the §7-related issue would depend on the particular filing, the nature of the request, and the kind of decision(s) and course(s) of action regarding the proposed new technology or service that may be deemed appropriate under the circumstances.

5. The Commission proposes adopting a new subpart in part 1 that sets forth specific procedures and timetables for action with respect to requests in petitions or applications for §7 consideration. These procedures and timetables are designed to ensure that the Commission or Bureau/Office identifies and moves swiftly to promote new technologies and services that are in the public interest. These new rules would not replace or substitute for the Commission’s existing rules for processing petitions and applications (e.g., the part 1 rules for rulemaking proceedings and for applications involving common carriers or wireless radio services, the part 25 rules for satellite service applications, the part 73 and 74 rules for broadcast service applications, among many other rule parts dealing with applications).

Instead, they would specify additional steps to ensure that timely decisions are made on §7 requests suited to serve the public interest.

6. Section 7 establishes a timeline by which the Commission must determine