

Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 CAA. Accordingly, this proposed action merely approves the state's law as meeting Federal requirements and does not impose additional requirements beyond those imposed by the state's law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
 - 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);
 - 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 the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
 - Does not provide the 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, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not

impose substantial direct costs on tribal governments or preempt tribal law. This SIP revision is not approved to apply in Indian reservations in the State, or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: January 4, 2017.

Dennis J. McLerran,

Regional Administrator, Region 10.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting a Rulemaking Proceeding

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

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa-14(c)(2)(B), notice is hereby given concerning the reasons for not conducting a rulemaking proceeding to add neurological disorders or conditions as injuries associated with seasonal influenza vaccines to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT:

Narayan Nair, MD, Director, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 8N146B, Rockville, Maryland 20857, or by telephone 301-443-6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, (Vaccine Act), Title III of Public Law 99-660, established the National

Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines.¹ Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. To gain entitlement to compensation under VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death in one of the following ways (unless another cause is found): (1) By proving that the first symptom of an injury or condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine; (2) by proving vaccine causation, if the injury or condition is not on the Table or did not occur within the time period specified on the Table; or (3) by proving that the vaccine significantly aggravated a pre-existing condition.

The statute authorizing VICP provides for the inclusion of additional vaccines in VICP when they are recommended by the Centers for Disease Control and Prevention for routine administration to children.² Consistent with section 13632(a)(3) of Public Law 103-66, the regulations governing VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines.³ The statute authorizing VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table.⁴ Finally, the Vaccine Act provides that:

[a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) Receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission, whichever occurs first, the Secretary shall conduct a rule-making proceeding on the matters proposed in the petition or publish

¹ 42 U.S.C. 300aa-10 *et seq.*

² Section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(e)(2).

³ 42 CFR 100.3(c)(8).

⁴ Sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa-14(c) and 300aa-14(e)(2).

in the **Federal Register** a statement or reasons for not conducting such proceeding.⁵

On January 28, 2016, a private citizen submitted a petition to the Department of Health and Human Services (HHS) requesting that: (1) Any adverse neurological disorder or condition be added to the Table for the seasonal influenza vaccines; and (2) if any adverse neurological disorder or condition was too broad in scope, then at least anaphylaxis, Shoulder Injury Related to Vaccine Administration (SIRVA), vasovagal syncope, multiple sclerosis (MS), Guillain-Barré Syndrome (GBS), transverse myelitis (TM), and myelitis be added to the Table for the seasonal influenza vaccine. The petitioner asserted that based on Vaccine Adverse Event Reporting System (VAERS) data and Department of Justice (DOJ) quarterly reports on vaccine settlements, which were presented at Commission meetings, there is sufficient evidence to add these conditions as injuries associated with the seasonal influenza vaccine to the Table. The petitioner did not provide any medical or scientific literature to accompany the request.

Pursuant to the Vaccine Act, the petition was referred to the Commission on June 3, 2016. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table to include “any adverse neurological disorder or condition,” MS, TM, or myelitis as injuries associated with seasonal influenza vaccines as requested in the petition.

The petitioner requested the addition of any adverse neurological disorder or condition to the Table for the seasonal influenza vaccine. The petitioner alleged that the DOJ quarterly reports on vaccine settlement cases and VAERS data support the inclusion of all of these conditions to the Table. However, neither of these sources of data is sufficient to modify the Table. The DOJ quarterly report is the report that DOJ provides and discusses at the quarterly Commission meetings and is made available to the public at <http://www.hrsa.gov/advisorycommittees/childhoodvaccines/meetings.html>. The report includes a list of adjudicated settlements for the applicable quarter by vaccine and alleged injury, and time frame from petition filing to settlement filing. In negotiated settlements between the parties, HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury. These settlements are not an

admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner’s alleged injury, and, in settled cases, the Court does not determine that the vaccine caused the injury. Therefore, a settlement cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Thus, information from negotiated settlements cannot be used to establish that vaccines cause certain injuries.

The purposes of VAERS data are to: Detect new, unusual, or rare vaccine adverse events; identify potential patient risk factors for particular types of adverse events; identify vaccine lots with increased numbers or types of reported adverse events; and assess the safety of newly licensed vaccines. The VAERS data are considered a useful tool in vaccine safety, but VAERS reports by themselves generally cannot demonstrate that vaccines cause injuries.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiologic, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by VICP. The results of this review were published in the 2012 IOM Report, “*Adverse Effects of Vaccines: Evidence and Causality*.” This report reviewed 8 of the 12 vaccines covered by the VICP and provided 158 causality conclusions. The 2012 IOM Report reviewed the medical and scientific literature regarding a causal relationship between seasonal influenza vaccines and the following conditions: Encephalopathy, encephalitis, seizures, acute disseminated encephalomyelitis, TM, optic neuritis, neuromyelitis optica, MS, MS relapse, GBS, chronic inflammatory demyelinating polyneuropathy, Bell’s palsy, brachial neuritis, and small fiber neuropathy. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and the above conditions. Therefore, “any adverse neurological disorder or condition,” as suggested by the petitioner will not be added as injuries caused by the seasonal influenza vaccine to the Table since the medical and scientific literature is not sufficient to support this change.

The petitioner also requested that certain conditions be added to the Table if “any adverse neurological disorder or condition” could not be added to the Table. These conditions include: Anaphylaxis, SIRVA, vasovagal syncope, MS, GBS, TM, and myelitis. The petitioner stated that VAERS and settlement data from quarterly reports support the inclusion of these

conditions for seasonal influenza vaccines to the Table. However, as explained above, the VAERS data and the DOJ quarterly report do not demonstrate that vaccines cause injuries and do not establish causality. As stated previously, the 2012 IOM Report reviewed the medical and scientific literature regarding causal relationships between seasonal influenza vaccines and MS, TM, and myelitis. The IOM concluded that the evidence is inadequate to accept or reject a causal relationship between influenza vaccines and these conditions.

More recent studies support the lack of an association between the seasonal influenza vaccine and neurologic conditions, such as MS. The Williamson, et al. study found no substantiation to reports suggesting a link between MS and vaccines and that most of the studies that purported an increased risk of MS or relapse of MS after vaccination were small case series, which are methodologically less robust than other epidemiologic studies.⁶ In addition, Langer-Gould, et al. conducted a nested case control study that found no long-term association between vaccines and MS or other central nervous system acquired demyelinating syndromes.⁷ Therefore, MS, TM, and myelitis will not be added to the Table as injuries associated with the seasonal influenza vaccine since the medical and scientific literature is not sufficient to support those changes.

HHS proposed certain changes to the Vaccine Injury Table in a Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on July 29, 2015 (80 Fed. Reg. 45132 (July 29, 2015)). Among other proposed changes, anaphylaxis, SIRVA, GBS, and vasovagal syncope were proposed to be added as injuries for seasonal influenza vaccines. HHS is adding these injuries with the final rule, titled “National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table,” concurrently publishing in the **Federal Register**.

In conclusion, there is no reliable evidence to support the addition of “any adverse neurological disorder or condition,” MS, TM, or myelitis to the Table as injuries associated with the seasonal influenza vaccine. Therefore, the Table will not be amended at this time to include those injuries on the Table.

⁶ Williamson et al. Vaccines in Multiple Sclerosis, *Curr Neurol Neurosci Rep* 2016 16:36.

⁷ Langer-Gould et al., Vaccines and the risk of MS and other CNS Demyelinating Diseases, *JAMA Neurol.* 2014;71(12): 1506–13.

⁵ Section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2).

Dated: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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DEPARTMENT OF HOMELAND SECURITY

48 CFR Parts 3001, 3002, 3024, and 3052

[Docket No. DHS-2017-0008]

RIN 1601-AA79

Homeland Security Acquisition Regulation (HSAR); Privacy Training (HSAR Case 2015-003)

AGENCY: Office of the Chief Procurement Officer, Department of Homeland Security (DHS).

ACTION: Proposed rule.

SUMMARY: DHS is proposing to amend the Homeland Security Acquisition Regulation (HSAR) to add a new subpart, update an existing clause, and add a new contract clause to require contractors to complete training that addresses the protection of privacy, in accordance with the Privacy Act of 1974, and the handling and safeguarding of Personally Identifiable Information and Sensitive Personally Identifiable Information.

DATES: Interested parties should submit written comments to one of the addresses shown below on or before March 20, 2017, to be considered in the formation of the final rule.

ADDRESSES: Submit comments identified by HSAR Case 2015-003, Privacy Training, using any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>.

Submit comments via the Federal eRulemaking portal by entering "HSAR Case 2015-003" under the heading "Enter Keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "HSAR Case 2015-003." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "HSAR Case 2015-003" on your attached document.

- *Fax:* (202) 447-0520
- *Mail:* Department of Homeland Security, Office of the Chief Procurement Officer, Acquisition Policy and Legislation, ATTN: Ms. Candace Lightfoot, 245 Murray Drive, Bldg. 410 (RDS), Washington, DC 20528.

Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal information provided. To confirm receipt of your comment(s), please check <http://www.regulations.gov>, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Candace Lightfoot, Procurement Analyst, DHS, Office of the Chief Procurement Officer, Acquisition Policy and Legislation at (202) 447-0882 or email HSAR@hq.dhs.gov. When using email, include HSAR Case 2015-003 in the "Subject" line.

SUPPLEMENTARY INFORMATION:

I. Background

DHS contracts currently require contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. This training is completed upon award of the procurement and at least annually thereafter.

DHS is proposing to (1) include Privacy training requirements in the HSAR and (2) make the training more easily accessible by hosting it on a public Web site. This approach ensures all applicable DHS contractors and subcontractors are subject to the same requirements while removing the need for Government intervention to provide access to the Privacy training.

This proposed rule standardizes the Privacy training requirement across all DHS contracts by amending the HSAR to:

(1) Add the terms "personally identifiable information" and "sensitive personally identifiable information" at HSAR 3002.1, Definitions. The definition of "personally identifiable information" is taken from OMB Circular A-130 Managing Information as a Strategic Resource,¹ published July 27, 2016. The definition of "sensitive personally identifiable information" is derived from the DHS lexicon, Privacy Incident Handling Guidance, and the Handbook for Safeguarding Sensitive Personally Identifiable Information. These definitions are necessary because these terms appear in proposed HSAR

3024.70, Privacy Training and HSAR 3052.224-7X, Privacy Training.

(2) Add a new subpart at HSAR 3024.70, Privacy Training addressing the requirements for privacy training. HSAR 3024.7001, Scope identifies the applicability of the subpart to contracts and subcontracts. HSAR 3024.7002, Definitions defines the term "handling." The definition of "handling" was developed based upon a review of definitions for the term developed by other Federal agencies. HSAR 3024.7003, Policy identifies when contractors and subcontracts are required to complete the DHS privacy training. This subsection also requires the submission of training completion certificates for all contractor and subcontractor employees as a record of compliance. HSAR 3024.7004, Contract Clause, identifies when Contracting Officers must insert HSAR 3052.224-7X Privacy Training in solicitations and contracts. DHS welcomes respondents to offer their views on the following questions in particular:

A. What burden, if any, is associated with the requirement to complete DHS-developed privacy training?

B. What value, if any, is associated with providing industry the flexibility to develop its own privacy training given a unique set of Government requirements?

(3) Amend sub paragraph (b) of the HSAR 3052.212-70, Contract Terms and Conditions Applicable to DHS Acquisition of Commercial Items to add HSAR 3052.224-7X, Privacy Training. This change is necessary because HSAR 3052.224-7X is applicable to the acquisition of commercial items; and

(4) Add a new subsection at HSAR 3052.224-7X, Privacy Training to provide the text of the proposed clause. The proposed clause requires contractor and subcontractor employees to complete privacy training before accessing a Government system of records; handling Personally Identifiable Information (PII) or Sensitive PII (SPII); or designing, developing, maintaining, or operating a Government system of records. The training shall be completed within thirty (30) days of contract award and on an annual basis thereafter. The contractor shall maintain copies of training certificates for all contractor and subcontractor employees as a record of compliance and provide copies of the training certificates to the contracting officer. Subsequent training certificates to satisfy the annual privacy training requirement shall be submitted via email notification not later than October 31st of each year. The contractor shall attach training certificates to the email

¹ OMB Circular A-130 *Managing Information as a Strategic Resource* is accessible at <https://www.whitehouse.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf>.