Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

* * * * *

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 14. Section 73.16 is amended by revising paragraph (l)(1) to read as follows:

§ 73.16 Transfers.

* * * * *

(l) * * *

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.,* prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

* * * * *

■ 15. Section 73.17 is amended as follows:

■ a. In paragraphs (a)(1)(iii) and (a)(3)(v) by adding ''or other storage container'' after ''freezer''.

■ b. By revising paragraph (a)(1)(v).

■ c. By adding paragraph (a)(8).

■ d . By revising paragraph (b).

■ e. By revising paragraph (c).

The revision and additions read as follows:

§ 73.17 Records.

(a) * * *

(1) * * *

(v) The select agent used, purpose of use, and, when applicable, final disposition,

* * * * *

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

* * * * *

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

Dated: January 9, 2017.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2017–00726 Filed 1–18–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

RIN 0906–AB01

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

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

ACTION: Final rule.

SUMMARY: On July 29, 2015, the Secretary of Health and Human Services (the Secretary) published in the **Federal Register** a Notice of Proposed Rulemaking (NPRM) to amend the regulations governing the National Vaccine Injury Compensation Program (VICP or program) by proposing revisions to the Vaccine Injury Table (Table). The Secretary based the Table revisions primarily on the 2012 Institute of Medicine (IOM) report, ''Adverse Effects of Vaccines: Evidence and Causality,'' the work of nine HHS workgroups who reviewed the IOM findings, and consideration of the Advisory Commission on Childhood Vaccines' (ACCV) recommendations. The Secretary amends the Table through the changes in this final rule. These changes will apply only to petitions for compensation under the VICP filed after this final rule becomes effective.

DATE: This rule is effective February 21, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Narayan Nair, 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 persons thought to be injured by vaccines. The statute governing the VICP has been amended several times since 1986 and is hereinafter referred to as ''the 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 designated as the ''Respondent.'' The Court, acting through judicial officers called Special Masters, makes decisions 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 a time 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 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)).

In prior Table revisions, the Secretary determined that the appropriate framework for making changes to the Table is to make specific findings as to the illnesses or conditions that can reasonably be determined, in some circumstances, to be caused or significantly aggravated by the vaccines under review and the circumstances under which such causation or aggravation can reasonably be determined to occur. The Secretary continues this approach through the use of the 2012 IOM report, the work of the nine workgroups who reviewed the IOM findings, and consideration of the ACCV's recommendations. After consultation with the ACCV, the Secretary may modify the Table by promulgating regulations, with notice and opportunity for a public hearing and at least 180 days of public comment. *See* 42 U.S.C. 300aa–14(c) and (d).

II. Summary of the Final Rule

After the IOM released its 2012 report, 9 HHS workgroups comprising HRSA and Centers for Disease Control and Prevention (CDC) medical staff reviewed IOM's conclusions for 158 vaccine-adverse events, as well as any newly published scientific literature not contained in the report, and developed a set of proposed changes to the Table and its definitional counterpart, the Qualifications and Aids to Interpretation (QAI). For the vast majority of the vaccine-adverse event pairs reviewed (135), the IOM determined that the evidence was inadequate to accept or reject a causal relationship. Considering the remaining IOM conclusions and the ACCV Guiding Principles, the Secretary in this final rule is adopting certain additions or changes to the Table where the scientific evidence either convincingly supports or favors acceptance of a causal relationship between certain conditions and covered vaccines, which are unchanged from the proposed rule. As required by the Act, the changes in the proposed rule were presented to the ACCV, which reviewed and concurred with the Table changes set forth in this final rule.

Additionally, the Secretary, following the recommendation of the ACCV, is finalizing the Table change, as proposed, to add the injury of Guillain-Barré Syndrome (GBS) for seasonal influenza vaccinations, which is consistent with the approach taken in the Countermeasures Injury Compensation Program (CICP). Studies have demonstrated a causal association between the monovalent 2009 H1N1 vaccine and the 1976 swine flu vaccine and GBS. These causal associations were the basis of the 2015 decision by the Secretary in the CICP Pandemic Influenza A Countermeasures Injury Table Final Rule (80 FR 47411) to include GBS as an injury associated with the 2009 H1N1 influenza. With respect to that vaccine, the Secretary found that there was compelling, reliable, and valid medical and scientific evidence of an association between the 2009 H1N1 vaccine and GBS, which is required to add an injury to the CICP's Injury Table. To date, the H1N1 antigen has been included in all seasonal influenza vaccines beginning with the 2010–2011 flu season. HHS notes that seasonal influenza vaccine formulations, unlike other vaccines, include multiple antigens that change from year-to-year, and enhanced surveillance activities to detect the incidence of GBS that occurred during the 2009 H1N1 pandemic may not occur with each virus strain change. In light of this information and other information as discussed in the proposed rule, the ACCV recommended that the Secretary add GBS consistent with one of its Guiding Principles: That where there is credible evidence to both support and reject a change to the Table, the change should, whenever possible, be made to the benefit of petitioners.

In addition, in the final rule, the Secretary adopts the proposed rule's new paragraph (b), *Provision that applies to all vaccines listed.* To streamline the Table, this paragraph includes any acute complication or sequela, including death, of the illness, disability, injury, or condition listed, as a Table injury (absent an exclusion as set forth under the QAI) rather than adding the provision to every line of the Table. To further streamline the Table, the Secretary deleted redundant wording in the various definitions, particularly with regard to any references to the presumption of causation, and the importance of the entire medical record. These elements have been included in paragraph (b) and are unchanged from the proposed rule. Finally, in this final rule, the Secretary adopts changes in the proposed rule that simplify and expand applicability of a provision that previously applied only to an encephalopathy. This provision, which indicates that idiopathic conditions do not rebut the Table presumption, now applies (through inclusion in paragraph (b)), to all injuries, while continuing to apply to an encephalopathy.

In this final rule, in addition to the changes described in the proposed rule, the Secretary has made the following non-substantive changes to the proposed rule for purposes of clarity:

a. Added headings to (c)(2)(ii) and (c)(3)(ii).

b. Moved text from the end of paragraph (c)(3)(ii)(C) to create a new (c)(3)(ii)(D).

c. Changed paragraphs (c)(11) and (12) by revising the sentence regarding organs other than the skin by adding ''the'' before '' disease'', inserting ''and'' after ''organ'', and moving '', not just mildly abnormal laboratory values'' to the end of the sentence.

d. Revised paragraph (c)(15)(i) by changing ''nine weeks'' to ''9 weeks''.

e. Changed paragraph (e)(1) (''Coverage Provisions'') for purpose of clarity and consistency with 42 U.S.C. 300aa–14(c)(4) by adding ''only'' before ''to petitions for compensation.''

The modified Table applies only to petitions filed under the VICP after the effective date of this final rule. Also, petitions must be filed within the applicable statute of limitations. The general statute of limitations applicable to petitions filed under the VICP, set forth in 42 U.S.C. 300aa–16(a),

continues to apply. However, the statute identifies a specific exception to this statute of limitations that applies when the effect of a revision to the Table makes a previously ineligible person eligible to receive compensation or when an eligible person's likelihood of obtaining compensation significantly increases. Under this exception, an individual who may be eligible to file a petition based on the revised Table may file the petition for compensation not later than 2 years after the effective date of the revision if the alleged injury or death occurred not more than 8 years before the effective date of the revision of the Table (42 U.S.C. 300aa–16(b)). This is true even if such individual previously filed a petition for compensation, and is thus an exception to the ''one petition per injury'' limitation of 42 U.S.C. 300aa–11(b)(2).

For any vaccine-adverse event pairs for which future scientific evidence develops to support a finding of a causal relationship, the Secretary will consider future rulemaking to revise the Table accordingly.

III. Comments and Responses

The NPRM provided a 180-day comment period that resulted in the receipt of 14 written comments—13 from individuals and one from a national organization. In addition, a public hearing on the proposed rule was held on January 14, 2016, during which a representative from the above mentioned national organization presented comments. The organization's oral comments were an expansion of the organization's previously submitted written comments. The Secretary carefully considered all received comments in the development of this final rule. Below is a summary of the comments and the Secretary's responses:

Comment: One commenter suggested that vaccines are unsafe, disagreed with the process for predicting vaccine harm to humans, and disagreed with the makeup of the ''group assembled to force changes in this Table,'' calling it a biased group.

Response: The United States has a long-standing vaccine safety program that closely monitors the safety of vaccines on an ongoing basis. Before vaccines are approved by the Food and Drug Administration (FDA), they are tested and studied extensively by scientists to help ensure they are safe and effective. After vaccines are approved, a critical part of the vaccine safety program is that the Centers for Disease Control and Prevention (CDC)'s Immunization Safety Office (ISO) and FDA monitor for possible vaccine side effects and conduct studies to determine whether health problems are caused by vaccines. CDC's ISO data show that the current U.S. vaccine supply is the safest in history.[1] Also, regulating clinical research and reviewing the safety of vaccines are responsibilities of the FDA, not the VICP, and changes in vaccine research and how vaccines are studied and tested are beyond the scope of this final rule.

As previously indicated, the Table revisions were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: Pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: A commenter suggested that shoulder injury related to vaccine administration (SIRVA) as defined in the QAI is too restrictive because the recipient's pain and reduced range of motion must be limited to the shoulder in which the intramuscular vaccine was administered. The commenter stated that such language was an artificial and unnecessary qualification, and expressed concern that recipients who have other symptoms, such as shoulder pain radiating to the neck or upper back, will not have the benefits of a Table injury. The commenter suggested that the QAI be expanded to include the shoulder and parts of the body attributed to that injury.

Response: SIRVA is a musculoskeletal condition caused by injection of a vaccine intended for intramuscular administration into the shoulder, and, as its name suggests, the condition is localized to the shoulder in which the vaccine was administered. In other words, pain in the neck or back without an injury to the shoulder in which an individual received a vaccine would not be considered SIRVA. Shoulder injuries that are not caused by injection occur frequently in the population. Thus, it is important to have a definition of SIRVA that is clearly associated with vaccine injection. The portion of the QAI limiting the pain and reduced range of motion to the shoulder in which the vaccine was administered is necessary to accurately reflect the vaccine-associated condition.

Comment: A commenter recommends revising the statute of limitations for filing complex cases, with additional consideration given to the aggravation of preexisting conditions not active until post vaccine(s).

Response: Revision of the statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: A commenter stated that there is a problem with the VICP's 3-year statute of limitations for filing a claim and the military's 5-year program titled, Temporary Disabled Retirement Listing (TDRL), where active duty military personnel injured by vaccines are placed. The commenter stated that the rules need to be amended and/or waivers granted to military personnel who are severely injured by vaccines so they can seek compensation for damages.

Response: Amending the Act's statute of limitations is not within the scope of this final rule.

Comment: A commenter recommended the addition of SIRVA to the vaccine court [sic]. The commenter also indicated a belief that SIRVA is due to lack of education on proper injection technique. The commenter further stated that the CDC should make SIRVA, which the commenter believes is 100 percent preventable, a priority.

Response: This final rule will add SIRVA as an injury associated with certain vaccines on the Table. In the VICP, claims are adjudicated by special masters in the Court. SIRVA prevention activities are not within the scope of this final rule.

Comment: A commenter recommended that the VICP transfer a fraction of its compensation responsibilities to pharmaceutical companies, which would incentivize these companies to develop safer vaccines to avoid claim compensation.

Response: The source of funding for the VICP is the Vaccine Injury Compensation Trust Fund (Trust Fund). The Trust Fund is funded by an excise tax on each dose of vaccines recommended by the CDC for routine administration to children. To the extent that the commenter is proposing a change to the funding mechanism for the VICP, effectuating such a change is beyond the scope of this final rule.

Comment: A commenter agreed with the Secretary's proposal that SIRVA injuries be added to the Table for the

[1] *http://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html*

measles, mumps, and rubella (MMR) and varicella vaccines that are currently administered only by percutaneous injection in case an intramuscular injection is available in the future. The commenter suggested that the Table make clear that SIRVA only pertains to intramuscular injection so there is no confusion with respect to vaccines administered using a different method. The commenter also suggested that syncope be added as an injury for vaccines that are administered by jet injectors. The commenter expressed support for the revision of the Table based on new medical findings and for the organizational changes to paragraph (b) of the Table.

Response: The Secretary agrees that SIRVA should be an injury listed on the Table for potential future formulations of MMR and varicella vaccines that are administered by intramuscular injection, and, therefore, has added SIRVA to the Table for those vaccines despite the fact that currently there are no MMR or varicella vaccines that are administered by intramuscular injection. As such, if an intramuscular formulation of those vaccines is developed in the future, the Table will not need to be amended to allow petitioners to potentially meet the definition for SIRVA in the QAI with respect to those vaccines. The QAI specifically states that SIRVA is a condition related to ''administration of a vaccine intended for intramuscular administration in the upper arm.'' Thus, the Secretary believes it is clear that to meet the definition of SIRVA in the QAI, the vaccine administered must be one intended for intramuscular injection in the upper arm.

The Secretary is not aware of any reliable and persuasive evidence demonstrating that syncope occurs following administration of a vaccine via a needleless jet device. While it may be plausible for syncope to occur with this route of administration, given the lack of evidence of syncope following administration of a vaccine via a needleless jet device, the Secretary will not include syncope as a Table injury for vaccines that are administered by a needleless jet device at this time. However, this does not preclude a claim alleging syncope after the administration of a vaccine via needleless jet device from being filed with the program as a non-Table injury.

Comment: One commenter opposed the revision of the Vaccine Injury Table's QAI for encephalopathy, stating that it is not based on sound science and that it creates a restrictive and exclusionary guideline that unfairly discriminates against children and adults born with certain genes or pre-existing conditions (which may be triggered or significantly aggravated following vaccination). The commenter further contends that due to lack of knowledge about biological mechanisms and high risk factors for vaccine injury, the proposed changes are without ethical, scientific, or legal justification.

Response: The Secretary respectfully disagrees with the comment that the revised definition for encephalopathy and the new definition for encephalitis in the QAI are not based on firm science. The previous definition of encephalopathy in the QAI was imprecise and did not include the comprehensive criteria used by medical providers, particularly specialists, to diagnose encephalopathy or encephalitis. In addition, the previous QAI did not include any definition for encephalitis, and, therefore, new and more accurate criteria and definitions were necessary. To develop precise definitions for the QAI, an extensive literature search was conducted for reliable, reputable, evidence-based criteria consistently used by medical specialists in the fields of infectious disease and neurology. The Secretary also evaluated information from organizations and publications to formulate definitions, including those responsible for publishing case definitions for the Vaccine Adverse Event Reporting System (2002) and other significant guidelines.

The commenter also stated that the proposed revisions create a restrictive and exclusionary guideline, unfairly discriminating against children and adults born with certain genes or pre-existing conditions which may be triggered or significantly aggravated following vaccination. The Secretary understands these concerns and agrees that individuals should not be disqualified from potentially receiving VICP compensation due to biodiversity and individual susceptibilities. Certain individuals may not meet the QAI definition, as it is impossible to develop a scientifically sound definition that allows for inclusion of every circumstance, particularly those that may arise when unique and sometimes complex pre-vaccination medical conditions exist.[2] However, individuals who do not meet the Table criteria are not precluded from filing a petition, and may be found entitled to receive compensation if they demonstrate that their condition was caused or significantly aggravated by a covered vaccine.

[2] 2012 IOM Report, pp. 52, and 82–84.

Comment: One commenter also noted that, historically, acute and chronic encephalopathy have been acknowledged as a serious complication of pertussis, measles and measles containing vaccines, and have been reported following receipt of other vaccines.

Response: With regard to this comment, it is important to note that the initial Table and QAI set forth in the 1986 Act reflected Congress's initial determination of vaccine-related injuries for whole cell diphtheria, tetanus, and pertussis (DTwP) vaccine, which is no longer used. Additionally, modifications to the Table and QAI by the Secretary in 1995 were based on scientific findings—the National Childhood Encephalopathy Study and its 10-year follow-up study—related to DTwP vaccine. The IOM committee's conclusions in both 1991 and 1994 were mixed regarding the statistically significant findings of encephalopathy in these studies. After reviewing the evidence, the National Vaccine Advisory Committee (NVAC) voted to remove encephalopathy from the Table. However, in the end, the Secretary, for both scientific and policy reasons, and with support of the ACCV, retained the condition on the Table, but clarified the definition of encephalopathy to make it more clinically precise.

While the initial Table and QAI were based on studies using DTwP vaccine, the acellular (aP) diphtheria, tetanus, and pertussis (DTaP) vaccine has been the primary formulation used in the United States since 1997 when it was recommended for routine use in children younger than 7 years of age. Current DTaP vaccines were developed because of concerns of reactogenicity with whole cell pertussis.

To date, no adequate scientific study has been published that demonstrates a causal relationship between either acellular pertussis vaccines or MMR vaccines and encephalopathy or encephalitis. As a result, in its most recent evaluation of adverse events after vaccines (2012), the IOM found that the evidence was inadequate to accept or reject a causal association between either acellular pertussis containing vaccines or MMR vaccines and encephalopathy or encephalitis. Of the large scale studies that have been conducted on DTaP, none have shown an increased risk of encephalopathy or encephalitis after receiving the DTaP vaccine. Furthermore, these studies have demonstrated a significant reduction in the number of common adverse events with acellular pertussis, such as crying and fevers, and less common ones, such as febrile seizures.

With regard to the MMR vaccine, because natural infection of measles, mumps and/or rubella virus is thought to lead to neurologic illness by damaging neurons through direct viral infection and/or reactivation, it is theorized that the same mechanisms may be responsible for vaccine-associated encephalopathy and encephalitis. However, of the studies examined and described by the IOM in its 2012 report, none identified causality between the MMR vaccine and encephalopathy or encephalitis. Similarly, the IOM concluded that the mechanistic evidence for an association is weak, based on knowledge about natural infection and only a few case reports. Accordingly, the Secretary does not agree that brain inflammation or acute and chronic encephalopathy have been acknowledged as a serious complication of either the DTaP or MMR vaccines. However, for the reasons discussed in the NPRM, the Secretary chose to retain these conditions in the revisions to the Table and QAI.

Comment: One commenter, when conveying views on acute encephalopathy as ''one of the most serious complications of vaccination . . .'' also referenced both encephalitis and encephalomyelitis in the discussion.

Response: The Secretary would like to clarify that encephalitis and encephalomyelitis (which is referred to as acute disseminated encephalomyelitis or ADEM) are distinct conditions. While they share some clinical characteristics, ADEM is a demyelinating condition with distinct differences from other types of encephalitis, as demonstrated on brain magnetic resonance imaging (MRI). The type of encephalitis that was initially attributed to DTwP was not described as demyelinating. Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on an MRI are distinct, with only ADEM displaying evidence of acute demyelination. For scientific accuracy, we have excluded ADEM from the Table definition of encephalitis.

Comment: One commenter, while applauding the expansion of the Vaccine Injury Table and agreeing with the IOM's recommendations, stated that the Table remains wholly inadequate to properly address ''the widespread epidemic of vaccine adverse events.'' The commenter stated that the reason for this is that science has been corrupted by commercial interests, by financial ties between industry, regulators, and academic institutions and that health care delivery has been compromised by financial ties between industry, physicians, and their trade publications.

Response: The Secretary believes that the revisions to the Table and QAI increase clarity and scientific accuracy regarding those injuries that will be afforded the Table's presumption of vaccine causation. As previously indicated, the revisions to the Table and QAI were based primarily on the 2012 IOM report which was developed after the IOM committee conducted a comprehensive review of the scientific literature on vaccines and adverse events. The committee charged with undertaking this review consisted of 16 members with expertise in the following fields: pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. The members of the review committee were subject to stringent conflict of interest criteria by the IOM. In addition, the proposed Table changes were developed by HHS workgroups and reviewed by the ACCV, the membership of which, by statute, reflects a variety of stakeholders with different perspectives.

Comment: One commenter stated that the Secretary should not make changes to the Vaccine Injury Table that would make it more difficult for ''victims'' to be compensated.

Response: The Secretary believes that the revisions to the Table and QAI set forth in this final rule, such as the addition of injuries, will make it easier for petitioners alleging injuries that meet the criteria in the Table and QAI to receive the Table's presumption of causation (which relieves them of having to prove that the vaccine actually caused or significantly aggravated the injury). This will make it easier for such petitioners to receive compensation under the VICP.

Comment: One commenter asked that additional consideration be given to the human papillomavirus (HPV) vaccination as a cause of postural orthostatic tachycardia syndrome (POTS), a condition where individuals can experience fainting and lightheadedness. The commenter also stated that the ''review period'' should be indefinite for the HPV vaccine.

Response: Like all vaccines used in the United States, HPV vaccines are required to go through years of safety testing before they are approved by the FDA. After they are approved and made available to the public, CDC and FDA continue to evaluate vaccines to ensure their safety. To date, there is no medical or scientific evidence that the HPV vaccine causes POTS and safety monitoring has not shown any other problems. Extending the review period for alleged injuries due to the HPV vaccine would require a statutory amendment to the Act's statute of limitations which is not within the scope of the final rule.

Comment: A commenter requested that food allergies be added to the Table asserting that food proteins that are present in vaccines cause the development of food allergies. The commenter also requested removal of the time limit that compensation is not provided for injuries or death that occurred more than ''8 years before the effective date of the revision of the Table'' because the commenter believes that ''food proteins in vaccines have been causing injury for decades.''

Response: The Secretary does not agree that food allergies should be added to the Table as injuries. HHS conducted a literature search of the major medical databases for any articles linking the development of food allergies to vaccinations (81 FR 17423, March 29, 2016). Despite an extensive search, HHS found no published research addressing any linkages or potential causality between vaccinations covered by VICP and the development of food allergies in any population. In addition, revision of the Act's statute of limitations would require a statutory amendment and thus is not within the scope of this final rule.

Comment: One commenter suggested that autism spectrum disorders be added to the Vaccine Injury Table. The commenter also requested removal of the time limit that compensation not be provided for injuries or death that occurred more than ''8 years before the effective date of the revision of the Table'' because the commenter believes that ''bovine milk contaminated vaccines have been causing injury for decades.''

Response: The Secretary does not agree that autism spectrum disorders should be added as an injury to the Table. The 2012 IOM report found that the epidemiologic and mechanistic evidence favored rejection of a causal relationship between the MMR vaccine and autism. Moreover, in opinions that were upheld on appeal to the U.S. Court of Appeals for the Federal Circuit, special masters of the U.S. Court of Federal Claims held that the MMR, whether administered alone or in conjunction with thimerosal-containing vaccines, is not a causal factor in the development of autism or autism spectrum disorders. In addition, revision of the Act's statute of limitations would require a statutory

amendment and thus is not within the purview of this final rule.

Comment: One commenter stated that thimerosal (a preservative added to vaccines) causes nerve damage.

Response: The Secretary disagrees with the comment that thimerosal in vaccines causes nerve damage to immunized individuals. Currently, no childhood vaccines used in the U.S. include thimerosal as a preservative, except for some formulations of influenza vaccine in multi-dose vials. When exposure to thimerosal occurs through vaccination, it is at a very low dose, which is readily eliminated from the body. Thimerosal has been used safely in vaccines since the 1930s. According to the CDC, scientists have been studying the use of thimerosal in vaccines for many years. They have not found any evidence that thimerosal causes any harm. Thimerosal use in medical products has a record of being very safe. Data from many studies show no evidence of harm caused by low doses of thimerosal in vaccines.[3]

Economic and Regulatory Impact

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 the Secretary must specifically consider the economic effect of a rule on small entities and analyze regulatory options that could lessen the impact of the rule.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues require special analysis.

The Secretary has determined that no resources are required to implement the requirements in this rule. Compensation will be made in the same manner. This final rule only lessens the burden of proof for potential petitioners. 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 Secretary has also determined that this final 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 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 rule is not being treated as a ''significant regulatory action'' as defined under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

As stated above, this final rule will modify the Vaccine Injury Table and its Qualifications and Aids to Interpretation based on legal authority.

Impact of the New Rule

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 the injury).

Paperwork Reduction Act of 1995

This final rule has no information collection requirements.

Dated: January 6, 2017.

James Macrae,

Acting Administrator, Health Resources and Services Administration.

Approved: January 9, 2017.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

List of Subjects in 42 CFR Part 100

Biologics, Health insurance, Immunization.

National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table

Therefore, for the reasons stated in the preamble, the Department of Health and Human Services amends 42 CFR part 100 as follows:

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. Revise § 100.3 to read as follows:

§ 100.3 Vaccine injury table.

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. 300aa–14(c)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such

[3] Following are referenced thimerosal studies:

1. Thimerosal Exposure in Infants and Developmental Disorders: A Retrospective Cohort Study in the United Kingdom Does Not Support a Causal Association by Nick Andrews et al. Pediatrics. September 2004. Vol 114: pp. 584–591. *http://pediatrics.aappublications.org/cgi/content/full/114/3/584.*

2. Pervasive Developmental Disorders in Montreal, Quebec, Canada: Prevalence and Links with Immunizations by Eric Frombonne et al. Pediatriacs. July 2006. Vol 118: e139–e150. *http://pediatrics.aappublications.org/cgi/content/full/118/1/e139.*

3. Association between Thimerosal-Containing Vaccine and Autism by Anders Hviid et al. Journal of the American Medical Association. October 2003. Vol 290: pp. 1763–1766. *http://jama.ama-assn.org/cgi/content/full/290/13/1763.*

4. Immunization Safety Review: Vaccines and Autism. Institute of Medicine. The National Academies Press: 2004. *http://www.iom.edu/Reports/2004/Immunization-SafetyReview-Vaccines-and-Autism.aspx.*

5. Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobulins and Risk of Autism by Cristofer Price et al. Pediatrics. September 2010. Vol 126: pp. 656–664, *http://pediatrics.aappublications.org/cgi/reprint* peds. 20100309v1.

6. Continuing Increases in Autism Reported to California's Developmental Services System by Robert Schechter et al. Archives of General Psychiatry. January 2008. Vol 65: pp. 19–24. *http://archpsyc.ama-assn.org/cgi/content/full/65/1/19.*

7. Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years by William Thompson et al. The New England Journal of Medicine. September 2007. Vol 357: pages 1281–1292. *http://www.nejm.org/doi/pdf/10.1056/NEJMoa071434.*

injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. Paragraph (b) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. Paragraph (c) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. Paragraph (d) of this section sets forth a glossary of terms used in paragraph (c).

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
I. Vaccines containing tetanus toxoid (*e.g.,* DTaP, DTP, DT, Td, or TT).	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2–28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (*e.g.,* DTP, DTaP, P, DTP-Hib).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
III. Vaccines containing measles, mumps, and rubella virus or any of its components (*e.g.,* MMR, MM, MMRV).	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	5–15 days (not less than 5 days and not more than 15 days).
	C. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
IV. Vaccines containing rubella virus (*e.g.,* MMR, MMRV).	A. Chronic arthritis	7–42 days (not less than 7 days and not more than 42 days).
V. Vaccines containing measles virus (*e.g.,* MMR, MM, MMRV).	A. Thrombocytopenic purpura	7–30 days (not less than 7 days and not more than 30 days).
	B. Vaccine-Strain Measles Viral Disease in an immunodeficient recipient.	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	≤12 months.
VI. Vaccines containing polio live virus (OPV)	A. Paralytic Polio.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
	B. Vaccine-Strain Polio Viral Infection.	
	—in a non-immunodeficient recipient	≤30 days.
	—in an immunodeficient recipient	≤6 months.
	—in a vaccine associated community case	Not applicable.
VII. Vaccines containing polio inactivated virus (*e.g.,* IPV).	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
VIII. Hepatitis B vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
IX. Haemophilus influenzae type b (Hib) vaccines.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
X. Varicella vaccines	A. Anaphylaxis	≤4 hours.
	B. Disseminated varicella vaccine-strain viral disease.	
	—Vaccine-strain virus identified	Not applicable.
	—If strain determination is not done or if laboratory testing is inconclusive.	7–42 days (not less than 7 days and not more than 42 days).
	C. Varicella vaccine-strain viral reactivation	Not applicable.
	D. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	E. Vasovagal syncope	≤1 hour.
XI. Rotavirus vaccines	A. Intussusception	1–21 days (not less than 1 day and not more than 21 days).
XII. Pneumococcal conjugate vaccines	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.

VACCINE INJURY TABLE—Continued

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
	B. Vasovagal syncope	≤1 hour.
XIII. Hepatitis A vaccines	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1 hour.
XIV. Seasonal influenza vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
	D. Guillain-Barré Syndrome	3–42 days (not less than 3 days and not more than 42 days).
XV. Meningococcal vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVI. Human papillomavirus (HPV) vaccines	A. Anaphylaxis	≤4 hours.
	B. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	C. Vasovagal syncope	≤1 hour.
XVII. 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.	A. Shoulder Injury Related to Vaccine Administration.	≤48 hours.
	B. Vasovagal syncope	≤1hour.

(b) *Provisions that apply to all conditions listed.* (1) Any acute complication or sequela, including death, of the illness, disability, injury, or condition listed in paragraph (a) of this section (and defined in paragraphs (c) and (d) of this section) qualifies as a Table injury under paragraph (a) except when the definition in paragraph (c) requires exclusion.

(2) In determining whether or not an injury is a condition set forth in paragraph (a) of this section, the Court shall consider the entire medical record.

(3) An idiopathic condition that meets the definition of an illness, disability, injury, or condition set forth in paragraph (c) of this section shall be considered to be a condition set forth in paragraph (a) of this section.

(c) *Qualifications and aids to interpretation.* The following qualifications and aids to interpretation shall apply to, define and describe the scope of, and be read in conjunction with paragraphs (a), (b), and (d) of this section:

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without sequela. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Encephalopathy.* A vaccine recipient shall be considered to have suffered an encephalopathy if an injury meeting the description below of an acute encephalopathy occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalopathy.* (A) For children less than 18 months of age who present:

(*1*) Without a seizure, an acute encephalopathy is indicated by a significantly decreased level of consciousness that lasts at least 24 hours.

(*2*) Following a seizure, an acute encephalopathy is demonstrated by a significantly decreased level of consciousness that lasts at least 24 hours and cannot be attributed to a postictal state—from a seizure or a medication.

(B) For adults and children 18 months of age or older, an acute encephalopathy is one that persists at least 24 hours and is characterized by at least two of the following:

(*1*) A significant change in mental status that is not medication related (such as a confusional state, delirium, or psychosis);

(*2*) A significantly decreased level of consciousness which is independent of a seizure and cannot be attributed to the effects of medication; and

(*3*) A seizure associated with loss of consciousness.

(C) The following clinical features in themselves do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia.

(D) Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy and in the absence of other evidence of an acute encephalopathy seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.

(ii) *Exclusionary criteria for encephalopathy.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, an encephalopathy shall not be considered to be a condition set forth in the Table if it is shown that the encephalopathy was caused by:

(A) An underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or

perinatal central nervous system (CNS) injury); or

(B) An acute event shown to be unrelated to the vaccine such as a head trauma, stroke, transient ischemic attack, complicated migraine, drug use (illicit or prescribed) or an infectious disease.

(3) *Encephalitis.* A vaccine recipient shall be considered to have suffered encephalitis if an injury meeting the description below of acute encephalitis occurs within the applicable time period and results in a chronic encephalopathy, as described in paragraph (d) of this section.

(i) *Acute encephalitis.* Encephalitis is indicated by evidence of neurologic dysfunction, as described in paragraph (c)(3)(i)(A) of this section, plus evidence of an inflammatory process in the brain, as described in paragraph (c)(3)(i)(B) of this section.

(A) Evidence of neurologic dysfunction consists of either:

(*1*) One of the following neurologic findings referable to the CNS: Focal cortical signs (such as aphasia, alexia, agraphia, cortical blindness); cranial nerve abnormalities; visual field defects; abnormal presence of primitive reflexes (such as Babinski's sign or sucking reflex); or cerebellar dysfunction (such as ataxia, dysmetria, or nystagmus); or

(*2*) An acute encephalopathy as set forth in paragraph (c)(2)(i) of this section.

(B) Evidence of an inflammatory process in the brain (central nervous system or CNS inflammation) must include cerebrospinal fluid (CSF) pleocytosis (>5 white blood cells (WBC)/mm^3 in children >2 months of age and adults; >15 WBC/mm3 in children <2 months of age); or at least two of the following:

(*1*) Fever (temperature ≥ 100.4 degrees Fahrenheit);

(*2*) Electroencephalogram findings consistent with encephalitis, such as diffuse or multifocal nonspecific background slowing and periodic discharges; or

(*3*) Neuroimaging findings consistent with encephalitis, which include, but are not limited to brain/spine magnetic resonance imaging (MRI) displaying diffuse or multifocal areas of hyperintense signal on T2-weighted, diffusion-weighted image, or fluid-attenuation inversion recovery sequences.

(ii) *Exclusionary criteria for encephalitis.* Regardless of whether or not the specific cause of the underlying condition, systemic disease, or acute event (including an infectious organism) is known, encephalitis shall not be considered to be a condition set forth in the Table if it is shown that the encephalitis was caused by:

(A) An underlying malignancy that led to a paraneoplastic encephalitis;

(B) An infectious disease associated with encephalitis, including a bacterial, parasitic, fungal or viral illness (such as herpes viruses, adenovirus, enterovirus, West Nile Virus, or human immunodeficiency virus), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing; or

(C) Acute disseminated encephalomyelitis (ADEM). Although early ADEM may have laboratory and clinical characteristics similar to acute encephalitis, findings on MRI are distinct with ADEM displaying evidence of acute demyelination (scattered, focal, or multifocal areas of inflammation and demyelination within cerebral subcortical and deep cortical white matter; gray matter involvement may also be seen but is a minor component); or

(D) Other conditions or abnormalities that would explain the vaccine recipient's symptoms.

(4) *Intussusception.* (i) For purposes of paragraph (a) of this section, intussusception means the invagination of a segment of intestine into the next segment of intestine, resulting in bowel obstruction, diminished arterial blood supply, and blockage of the venous blood flow. This is characterized by a sudden onset of abdominal pain that may be manifested by anguished crying, irritability, vomiting, abdominal swelling, and/or passing of stools mixed with blood and mucus.

(ii) For purposes of paragraph (a) of this section, the following shall not be considered to be a Table intussusception:

(A) Onset that occurs with or after the third dose of a vaccine containing rotavirus;

(B) Onset within 14 days after an infectious disease associated with intussusception, including viral disease (such as those secondary to non-enteric or enteric adenovirus, or other enteric viruses such as Enterovirus), enteric bacteria (such as Campylobacter jejuni), or enteric parasites (such as Ascaris lumbricoides), which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing;

(C) Onset in a person with a preexisting condition identified as the lead point for intussusception such as intestinal masses and cystic structures (such as polyps, tumors, Meckel's diverticulum, lymphoma, or duplication cysts);

(D) Onset in a person with abnormalities of the bowel, including congenital anatomic abnormalities, anatomic changes after abdominal surgery, and other anatomic bowel abnormalities caused by mucosal hemorrhage, trauma, or abnormal intestinal blood vessels (such as Henoch Scholein purpura, hematoma, or hemangioma); or

(E) Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease).

(5) *Chronic arthritis.* Chronic arthritis is defined as persistent joint swelling with at least two additional manifestations of warmth, tenderness, pain with movement, or limited range of motion, lasting for at least 6 months.

(i) Chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation recorded within 30 days after the onset of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination; and

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination; and

(C) Medical documentation of an antibody response to the rubella virus.

(ii) The following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile idiopathic arthritis, systemic lupus erythematosus, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders, and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's Syndrome, blood disorders, or arthralgia (joint pain), or joint stiffness without swelling.

(6) *Brachial neuritis.* This term is defined as dysfunction limited to the upper extremity nerve plexus (*i.e.,* its trunks, divisions, or cords). A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is

typically followed in days or weeks by weakness in the affected upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. Atrophy of the affected muscles may occur. The neuritis, or plexopathy, may be present on the same side or on the side opposite the injection. It is sometimes bilateral, affecting both upper extremities. A vaccine recipient shall be considered to have suffered brachial neuritis as a Table injury if such recipient manifests all of the following:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;

(ii) Weakness;

(A) Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.

(B) Nerve conduction studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

(7) *Thrombocytopenic purpura.* This term is defined by the presence of clinical manifestations, such as petechiae, significant bruising, or spontaneous bleeding, and by a serum platelet count less than 50,000/mm^3 with normal red and white blood cell indices. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uremic syndrome. Thrombocytopenic purpura does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, human immunodeficiency virus, adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. However, if culture or serologic testing is performed, and the viral illness is attributed to the vaccine-strain measles virus, the presumption of causation will remain in effect. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) *Vaccine-strain measles viral disease.* This term is defined as a measles illness that involves the skin and/or another organ (such as the brain or lungs). Measles virus must be isolated from the affected organ or histopathologic findings characteristic for the disease must be present. Measles viral strain determination may be performed by methods such as polymerase chain reaction test and vaccine-specific monoclonal antibody. If strain determination reveals wild-type measles virus or another, non-vaccine-strain virus, the disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur within 12 months after vaccination.

(9) *Vaccine-strain polio viral infection.* This term is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

(10) *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (*e.g.* tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time-frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (*e.g.* NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

(11) *Disseminated varicella vaccine-strain viral disease.* Disseminated varicella vaccine-strain viral disease is defined as a varicella illness that involves the skin beyond the dermatome in which the vaccination was given and/or disease caused by vaccine-strain varicella in another organ. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. If there is involvement of an organ beyond the skin, and no virus was identified in that organ, the involvement of all organs must occur as part of the same, discrete illness. If strain determination reveals wild-type varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table. If strain determination is not done or if the strain cannot be identified, onset of illness in any organ must occur 7– 42 days after vaccination.

(12) *Varicella vaccine-strain viral reactivation disease.* Varicella vaccine-strain viral reactivation disease is defined as the presence of the rash of herpes zoster with or without concurrent disease in an organ other than the skin. Zoster, or shingles, is a painful, unilateral, pruritic rash appearing in one or more sensory dermatomes. For organs other than the skin, the disease must be demonstrated in the involved organ and not just through mildly abnormal laboratory values. There must be laboratory confirmation that the vaccine-strain of the varicella virus is present in the skin or in any other involved organ, for example by oligonucleotide or polymerase chain reaction. If strain determination reveals wild-type

varicella virus or another, non-vaccine-strain virus, the viral disease shall not be considered to be a condition set forth in the Table.

(13) *Vasovagal syncope.* Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected vaccine. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant sequela. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously with vasovagal syncope. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: organic heart disease, cardiac arrhythmias, transient ischemic attacks, hyperventilation, metabolic conditions, neurological conditions, and seizures. Episodes of recurrent syncope occurring after the applicable time period are not considered to be sequela of an episode of syncope meeting the Table requirements.

(14) *Immunodeficient recipient.* Immunodeficient recipient is defined as an individual with an identified defect in the immunological system which impairs the body's ability to fight infections. The identified defect may be due to an inherited disorder (such as severe combined immunodeficiency resulting in absent T lymphocytes), or an acquired disorder (such as acquired immunodeficiency syndrome resulting from decreased CD4 cell counts). The identified defect must be demonstrated in the medical records, either preceding or postdating vaccination.

(15) *Guillain-Barré Syndrome (GBS).* (i) GBS is an acute monophasic peripheral neuropathy that encompasses a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time-frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires:

(A) Bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs;

(B) A monophasic illness pattern;

(C) An interval between onset and nadir of weakness between 12 hours and 28 days;

(D) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau); and,

(E) The absence of an identified more likely alternative diagnosis.

(iii) Fisher Syndrome (FS), also known as Miller Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires:

(A) Bilateral ophthalmoparesis;

(B) Bilateral reduced or absent tendon reflexes;

(C) Ataxia;

(D) The absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP, AMAN, or AMSAN);

(E) A monophasic illness pattern;

(F) An interval between onset and nadir of weakness between 12 hours and 28 days;

(G) Subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse; however, death may occur without a clinical plateau);

(H) No alteration in consciousness;

(I) No corticospinal track signs; and

(J) The absence of an identified more likely alternative diagnosis.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. Both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) To qualify as any subtype of GBS, there must not be a more likely alternative diagnosis for the weakness.

(vi) Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: chronic immune demyelinating polyradiculopathy (CIDP), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(d) *Glossary for purposes of paragraph (c) of this section*—(1) *Chronic encephalopathy.* (i) A chronic encephalopathy occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis.

(ii) Individuals who return to their baseline neurologic state, as confirmed by clinical findings, within less than 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis shall not be presumed to have suffered residual neurologic damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy or encephalitis.

(2) *Injected* refers to the intramuscular, intradermal, or

subcutaneous needle administration of a vaccine.

(3) *Sequela* means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(4) *Significantly decreased level of consciousness* is indicated by the presence of one or more of the following clinical signs:

(i) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);

(ii) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(iii) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(5) *Seizure* includes myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures, but not absence (petit mal), or pseudo seizures. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(e) *Coverage provisions.* (1) Except as provided in paragraph (e)(2), (3), (4), (5), (6), (7), or (8) of this section, this section applies only to petitions for compensation under the program filed with the United States Court of Federal Claims on or after February 21, 2017.

(2) Hepatitis B, Hib, and varicella vaccines (Items VIII, IX, and X of the Table) are included in the Table as of August 6, 1997.

(3) Rotavirus vaccines (Item XI of the Table) are included in the Table as of October 22, 1998.

(4) Pneumococcal conjugate vaccines (Item XII of the Table) are included in the Table as of December 18, 1999.

(5) Hepatitis A vaccines (Item XIII of the Table) are included on the Table as of December 1, 2004.

(6) Trivalent influenza vaccines (Included in item XIV of the Table) are included on the Table as of July 1, 2005. All other seasonal influenza vaccines (Item XIV of the Table) are included on the Table as of November 12, 2013.

(7) Meningococcal vaccines and human papillomavirus vaccines (Items XV and XVI of the Table) are included on the Table as of February 1, 2007.

(8) Other new vaccines (Item XVII of the Table) will be included in the Table as of the effective date of a tax enacted to provide funds for compensation paid with respect to such vaccines. An amendment to this section will be published in the **Federal Register** to announce the effective date of such a tax.

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 3160

[17X.LLWO310000.L13100000.PP0000]

RIN 1004–AE49

Onshore Oil and Gas Operations—Annual Civil Penalties Inflation Adjustments

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: This rule adjusts the level of civil monetary penalties contained in the Bureau of Land Management's regulations governing onshore oil and gas operations as required by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the ''Act''). The adjustments made by this final rule constitute the annual inflation adjustments contemplated by the Act, and are consistent with applicable Office of Management and Budget (OMB) guidance.

DATES: This rule is effective on January 19, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Wells, Division Chief, Fluid Minerals Division, 202–912–7143, for information regarding the BLM's Fluid Minerals Program. For questions relating to regulatory process issues, please contact Jennifer Noe, Division of Regulatory Affairs, at 202–912–7442. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week to contact the above individuals.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed the Act into law (Sec. 701 of Pub. L. 114–74). The Act requires agencies to:

1. Adjust the level of civil monetary penalties with an initial ''catch-up'' adjustment through an interim final rulemaking in 2016;

2. Make subsequent annual adjustments for inflation beginning in 2017; and

3. Report annually in Agency Financial Reports on these inflation adjustments.

In July 2016, the BLM issued an interim final rule that adjusted the level of civil monetary penalties with the initial ''catch-up'' adjustment, which is reflected in the table below in the ''Previous Penalty'' column.

With this final rule, the BLM is adjusting civil monetary penalties for inflation. The adjustments made by this rule are consistent with the requirements of the Act and OMB guidance.

The purpose of these adjustments is to maintain the deterrent effect of civil penalties found in existing regulations, in order to further the policy goals of the underlying statutes. The BLM has reviewed its existing regulations and determined that only the civil monetary penalties found at 43 CFR 3163.2 are subject to the Act's requirements.

The adjustments made by this final rule constitute the first annual adjustment contemplated by the Act, and include the following changes to the penalties:

CFR Citation	Description of the penalty	Previous penalty	Adjusted penalty
43 CFR 3163.2(a)	Failure to comply	$1,031	$1,048
43 CFR 3163.2(b)	If corrective action is not taken	10,314	10,483
43 CFR 3163.2(d)	If transporter fails to permit inspection for documentation	1,031	1,048
43 CFR 3163.2(e)	Failure to permit inspection, failure to notify	20,628	20,965
43 CFR 3163.2(f)	False or inaccurate documents; unlawful transfer or purchase	51,570	52,414
43 CFR 3163.2(g)(1)	Initial penalty under 43 CFR 3163.2(a) for a major violation	1,031	1,048
43 CFR 3163.2(g)(1)	Maximum penalty under 43 CFR 3163.2(a) for a major violation	2,063	2,097