

n = Number of valid test runs.
P = DQO indicator statistic, distance from the average measured CE value to the endpoints of the 95-percent (two-sided) confidence interval, expressed as a percent of the average measured CE value.
s = Sample standard deviation.
 $t_{0.975}$ = t-value at the 95-percent (two-sided) confidence level (see Table A-1).
 x_{avg} = Average measured CE value (calculated from all valid test runs).
 x_i = The CE value calculated from the *i*th test run.

TABLE A-1.—t-VALUES

Number of valid test runs, n	$t_{0.975}$	$t_{0.90}$
1 or 2	N/A	N/A
3	4.303	1.886
4	3.182	1.638
5	2.776	1.533
6	2.571	1.476
7	2.447	1.440
8	2.365	1.415
9	2.306	1.397
10	2.262	1.383
11	2.228	1.372
12	2.201	1.363
13	2.179	1.356
14	2.160	1.350
15	2.145	1.345
16	2.131	1.341
17	2.120	1.337
18	2.110	1.333
19	2.101	1.330
20	2.093	1.328
21	2.086	1.325

* * * * *

4.8 The LCL is calculated at an 80 percent (two-sided) confidence level as follows using Equation 11:

$$LC_1 = x_{avg} - \frac{t_{0.90}s}{\sqrt{n}} \quad \text{Eq. 11}$$

Where:

LC_1 = LCL at an 80-percent (two-sided) confidence level.

n = Number of valid test runs.

s = Sample standard deviation.

$t_{0.90}$ = t-value at the 80-percent (two-sided) confidence level (see Table A-1).

x_{avg} = Average measured CE value (calculated from all valid test runs).

* * * * *

Subpart JJJJ—[Amended]

■ 12. Section 63.3300 is amended by revising paragraph (a) to read as follows:

§ 63.3300 Which of my emission sources are affected by this subpart?

* * * * *

(a) Any web coating line that is stand-alone equipment under subpart KK of

this part (National Emission Standards for the Printing and Publishing Industry) which the owner or operator includes in the affected source under subpart KK.

* * * * *

Subpart OOOO—[Amended]

■ 13. Section 63.4281 is amended by:

■ a. Revising paragraph (d) introductory text.

■ b. Adding paragraphs (d)(4) to read as follows:

§ 63.4281 Am I subject to this subpart?

* * * * *

(d) Web coating lines specified in paragraphs (d)(1) through (4) of this section are not part of the affected source of this subpart.

* * * * *

(4) Any web coating line that coats or prints fabric or other textiles for use in flexible packaging and that is included in an affected source under subpart KK of this part (National Emission Standards for the Printing and Publishing Industry).

* * * * *

[FR Doc. 06-4821 Filed 5-23-06; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 102

RIN 0906—AA60

Smallpox Vaccine Injury Compensation Program: Smallpox (Vaccinia) Vaccine Injury Table

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

ACTION: Adoption of interim final rule as final rule with an amendment.

SUMMARY: This document adopts the Smallpox (Vaccinia) Vaccine Injury Table (the Table) Interim Final Rule as the Final Rule with an amendment, as follows: the Final Rule clarifies that, in order for the presumption of causation to apply, the time intervals listed on the Table refer specifically to the period in which the first symptom or manifestation of onset of injury must appear following administration of the smallpox vaccine or exposure to vaccinia, and that the time intervals listed have no relevance to time of diagnosis of the injury.

DATES: The Interim Final Rule, published on August 27, 2003, was

effective on that date, and is adopted as the Final Rule with an amendment effective May 24, 2006.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, (301) 443-2330.

SUPPLEMENTARY INFORMATION:

Background

The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Pub. L. 108-20, 117 Stat. 638, directed the Secretary of Health and Human Services (the Secretary) to establish the Smallpox Vaccine Injury Compensation Program (the Program). Secondary to other payers, the Program provides medical, lost employment income, and death benefits for eligible individuals who sustained covered injuries as a result of receiving smallpox vaccine or other covered countermeasures, or as a result of accidental exposure to vaccinia. Congress appropriated \$42 million in fiscal year (FY) 2003 for the administration of, and payment of benefits under, the Program. The Consolidated Appropriations Act of 2005 reduced this appropriation to \$22 million. The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2006 (Pub. L. 109-149) further reduced the Program's appropriation by \$10 million to a total of \$12 million.

Individuals who receive a smallpox vaccination under a Department of Health and Human Services (HHS), State, or local emergency response plan approved by HHS within the period described in the Secretary's Declaration, and who sustain a covered injury may be eligible for benefits under SEPPA. Individuals who contracted vaccinia through contact with such individuals or other eligible vaccinia contacts and who sustain a covered injury may also be eligible for benefits. In the case of death resulting directly from receipt of the smallpox vaccine or exposure to vaccinia by eligible individuals, certain of their survivors may be considered for death benefits. If an eligible individual who sustained a covered injury dies from another cause before payment of benefits has been made under the Program, the estate may qualify for payment of unreimbursed medical expenses incurred and employment income lost as a result of the covered injury, secondary to other payers. SEPPA directed the Secretary to establish a table identifying adverse effects (including injuries, disabilities,

conditions, and deaths) that shall be presumed to result from the administration of, or exposure to, the smallpox vaccine, and the time interval in which the first symptom or manifestation of each listed injury must appear in order for such presumption to apply. An Interim Final Rule for the Table was published in the **Federal Register** on August 27, 2003 (68 FR 51492), with public comments sought on these provisions.

Based on the comments received, this Final Rule clarifies that the Table is not the sole standard for determining medical eligibility for benefits under the Program. Therefore, an individual who sustains an injury that is not on the Table or not within the timeframes on the Table, and believes it was caused by a smallpox vaccination, is encouraged to submit a Request Package to the Program. This Final Rule makes it clear that the time intervals on the Table refer specifically to the first symptom or manifestation of onset of illness or injury, not to the date of the diagnosis. It also clarifies that any component of a smallpox vaccine, not only the vaccinia, could be the possible cause of a covered injury. Further, this regulation updates the Interim Final Rule to reflect that the Secretary has extended the effective period of the Declaration Regarding Administration of Smallpox Countermeasures (the Declaration). Finally, this Final Rule also updates the change in name of the Special Programs Bureau to the Healthcare Systems Bureau; and provides the new address of the Program Office.

Discussion of Comments

The public comment period ended on October 27, 2003. HHS received a total of 11 public comments. Four were from professional associations; three were from medical professionals; two were from the general public; one was from a State health department; and one was from a nonprofit community health organization. The issues raised and HHS's responses appear below.

A. Time Intervals for the First Symptom or Manifestation of Onset of Injury

The Secretary received two comments suggesting that the time intervals listed on the Table be lengthened. One commenter requested that the Secretary extend the time limit for the onset of myocarditis and pericarditis from 21 days to 60 days. The other commenter indicated concern that the time intervals listed on the Table seem potentially short, and should be determined in consultation with the Centers for Disease Control and Prevention (CDC) and the military regarding all the Table

time intervals, independent of how long it takes for a scab to fall off. The Secretary received a third comment related to the time intervals on the Table requesting an appeal process to the Table time intervals.

The Secretary does not concur with changing the time intervals on the Table, whether it be for the onset of myocarditis or pericarditis from 21 to 60 days, or any other seemingly short time intervals. The Secretary did consult with the Department of Defense (DoD) and CDC, as well as with other HHS components and the private sector. Their scientific data support the time intervals as specified on the Table. The commenters did not provide evidence to support lengthening the time intervals beyond that which the Secretary had already considered and, therefore, they remain as currently listed. However, as discussed below, if any individual has symptoms that manifest outside of those time intervals, he or she may still be considered for benefits under the Program.

The third commenter expressed the hope that the Table permits adequate time for injured individuals to seek compensation, and recommended that language be added to the regulations to provide an avenue for appeal to the timeframes established in the Table, should an individual become ill or exhibit symptoms related to the vaccine beyond the established Table timeframes.

The Secretary wishes to emphasize that an injury that manifests itself outside of the timeframe listed on the Table may still be a covered injury. The Secretary recognizes that symptoms can occur subsequent to the Table timeframes in some cases. In this event, the individual may be found medically eligible if he or she submits evidence to show that it is more likely than not that the smallpox vaccine or other covered countermeasure, or the vaccinia contracted from accidental vaccinia exposure, actually caused the injury. SEPPA does not provide an avenue for appeal of the timeframes established in the Table. Thus, the Secretary disagrees with the commenter that there is a need for an appeal process for the time intervals. However, the Secretary has established a reconsideration process for re-review of the Program's determinations on medical/program and financial eligibility requirements through the Administrative Regulations for this Program published in the **Federal Register** on December 16, 2003. If a requester is not satisfied with the Program's decisions, the requester has the right to seek reconsideration of any adverse determination.

There were two additional comments regarding time intervals. One commenter wanted to make sure that HHS clarifies that the time intervals relate to the timeframe of the first symptom or manifestation of onset of injury, not to the timeframe of the diagnosis. The Secretary agrees with this comment and has clarified this issue by inserting appropriate language into this Final Rule.

The other commenter requested that the time intervals of 21 days be extended because it may take 6 to 8 weeks for the scab at the vaccination site to fall off. The Secretary does not agree to change the time intervals on the Table because these timeframes are not related to the time it takes for the scab to fall off spontaneously.

B. Additions of Injuries to the Table

There were three comments pertaining to the injuries listed on the Table. Two comments suggested that the Table should be amended to include myocardial infarction and tremors, respectively. The other commenter indicated that the list of injuries limited to those published in the August 27, 2003, Interim Final Rule, was incomplete.

The Secretary does not concur with these comments. At this time, there is no clear scientific evidence to support the inclusion of myocardial infarction, tremors, or other conditions as additional Table injuries, and the commenters did not provide additional evidence showing it would be appropriate to add more Table injuries. Should an individual have any injury believed to have resulted from the administration of, or exposure to, the smallpox vaccine that is not listed on the Table, he or she may nevertheless be eligible for benefits and should submit a request to the Program.

C. The Documentation Requirements

One commenter raised the issue that the Table regulations exceed the statute's requirements in terms of medical injury documentation burden and related cost. The commenter believes that these regulations are far more onerous than SEPPA requires, specifying that the issues of documenting method of treatment, identification of injury, etc., are not even referenced in the statute. The commenter stated that the burdensome and costly requirements for first responders should immediately be rescinded.

The Secretary disagrees with the commenter that the documentation requirement is onerous and exceeds legislative intent. The specific comment

relates to the requirement for a treatment plan in order to be considered for a Table injury. This language appears in five of the twelve Table injuries. The requirement for a treatment plan is case-specific and applies only in certain circumstances where there is an issue of needed long-term medical/surgical care. Requesters do not need to provide one in order to be considered for a Table injury.

The commenter also wrote that first responders are obligated to pay out of their own pockets for immediate treatment and again for a detailed surgical treatment plan. Section 264(b) of the Smallpox Emergency Personnel Protection Act of 2003 establishes that the government is the payer of last resort after all other payments have been or will be made to an individual for medical care directly resulting from an injury caused by the smallpox vaccination. Individuals are reimbursed for their out-of-pocket medical expenses in accordance with the Act.

D. Other Issues Raised by Commenters

One commenter raised the concern that the Table regulations cover only those injuries caused by the vaccinia virus and not all components of the smallpox vaccine. Another commenter was concerned about the scope of the Program and if it would cover the general population.

In reference to the issue of the components in the smallpox vaccine, the Secretary concurs that the components of a smallpox vaccine may cause a covered injury. Therefore, the Secretary has clarified in this final regulation that a covered injury can be caused not only by vaccinia, but by any component or constituent of the smallpox vaccine.

In response to the concern about the scope of the legislation, SEPPA only covers individuals who are members of HHS-approved smallpox emergency response plans and individuals who contracted vaccinia from them or from other eligible contacts. SEPPA is not designed to provide benefits to the general population.

Explanation of Provisions

Some of the comments received indicate to the Secretary that there may be confusion as to the significance of the Table. Therefore, this Final Rule clarifies that having an injury listed on the Table is only *one* of the ways that an individual can show medical eligibility for Program benefits. The Secretary emphasizes that the purpose of the Table is merely to provide potential requesters who can demonstrate that they sustained a Table

injury within the specified time interval with the *presumption* that the smallpox vaccine caused the injury. However, sustaining an injury not listed on the Table (including an injury resulting from administration of another covered countermeasure), or manifesting a Table injury outside of the time interval listed, simply means that the presumption does not apply. In those cases, the individual must show that it is more likely than not (*i.e.*, by a preponderance of the evidence), that administration of the smallpox vaccine (or other covered countermeasure), or exposure to the vaccine in the case of contacts, was the cause of the injury. The Secretary encourages such individuals to file a request for benefits. The Program has found individuals with Table or non-Table injuries to be medically eligible.

As previously mentioned, this Final Rule also clarifies that the time intervals listed on the Table refer specifically to the period in which the first symptom or manifestation of onset of injury must appear following administration of the smallpox vaccine or exposure to vaccinia, in order for the presumption of causation to apply. The time intervals listed have no relevance whatsoever to when the injury is diagnosed.

Thus, the Secretary herein amends § 102.21(a) of the Interim Final Rule by adding language to the subheading of the Table that lists the time intervals. This additional language makes it clear that these time intervals refer only to the first symptom or manifestation of onset of the injury, not to the time interval within which a diagnosis of the injury must be made.

The Secretary also wishes to make it clear that a covered injury can be caused not only by the vaccinia component of the smallpox vaccine, but by any component or constituent of the vaccine.

Further, this Final Rule updates the effective period of the Secretary's Declaration. The Secretary has amended the effective period of the Declaration by extending it each year. The Secretary will continue to publish a Notice in the **Federal Register** as needed to update any further amendments to the effective period. These amendments to the Declaration are made pursuant to the Secretary's authority under section 261(a)(5) of SEPPA (section 224(p)(2)(A) of the Public Health Service Act).

Additionally, this Final Rule reflects the change in name of the Special Programs Bureau, which has been renamed the Healthcare Systems Bureau. Finally, this regulation updates the address of the Program Office. The new address, to which all mail to the Program should be sent, whether by

U.S. Postal Service, commercial carrier, or private courier service, is: Parklawn Building, Room 11C-06, 5600 Fishers Lane, Rockville, Maryland 20857.

Justification of Waiver of Delay of Effective Date

The Secretary has found that a delay in the effective date of this Final Rule with an amendment is unnecessary and contrary to the public interest. The adoption of the Interim Final Rule as a Final Rule reflects an amendment and clarifications that are a result of comments received on the Interim Final Rule and, therefore, will be helpful to requesters without imposing additional burdens. It has no effect on any individual's rights or responsibilities.

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 of 1980 (RFA), 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, of costs, of benefits, of incentives, of equity, and of 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 minimal resources are required to implement the provisions included in this regulation. Therefore, in accordance with the RFA, and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this Final Rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. This rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

Unfunded Mandates Reform Act of 1995

The Secretary has determined that this Final Rule will not have effects on State, local, or tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

Federalism Impact Statement

The Secretary has also reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have "federalism implications." The rule does not "have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

Impact on Family Well-Being

This rule will not adversely affect the following elements of family well-being: 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. In fact, this Final Rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that injured persons (or their survivors who are eligible to receive compensation) receive benefits without a corresponding burden being imposed on them.

Paperwork Reduction Act

The information collection requirements remain unchanged.

List of Subjects in 42 CFR Part 102

Benefits, Biologics, Compensation, Immunization, Public health, Smallpox, Vaccinia.

Dated: November 14, 2005.

Elizabeth M. Duke,
Administrator.

Approved: December 22, 2005.

Michael O. Leavitt,
Secretary.

Editorial Note: This document was received at the Office of the Federal Register on May 18, 2006.

■ For the reasons stated above, the Secretary is adopting the Interim Final Rule adding 42 CFR part 102, published at 68 FR 51492 on Wednesday, August 27, 2003, as a Final Rule with the following amendment:

PART 102—SMALLPOX COMPENSATION PROGRAM

■ 1. The authority citation for part 102 continues to read as follows:

Authority: 42 U.S.C. 216, 42 U.S.C. 239–239h.

■ 2. In section 102.21, the table in paragraph (a) is amended by adding the following sentence at the end of the time interval description subheading:

§ 102.21 Smallpox (Vaccinia) Vaccine Injury Table.

(a) * * *

Please note that these time intervals do not refer to time periods for the date of diagnosis of the injury.

* * * * *

[FR Doc. 06–4761 Filed 5–23–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 102

RIN 0906—AA61

Smallpox Vaccine Injury Compensation Program: Administrative Implementation

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

ACTION: Adoption of interim final rule as final rule with amendments.

SUMMARY: This document adopts the Smallpox Vaccine Injury Compensation Program (the Program) Administrative Implementation Interim Final Rule as the Final Rule with amendments, as follows: explains how the term "child" survivor is defined; updates the effective period of the Secretary's Declaration Regarding Administration of Smallpox Countermeasures (the Declaration); corrects an error in § 102.20(d) to clarify that one of the Smallpox (Vaccinia) Vaccine Injury Table requirements to establish a covered Table injury is the first symptom or manifestation of onset of the injury in the Table time period specified; reflects the change in name from the Special Programs Bureau to the Healthcare Systems Bureau; provides the new address of the Bureau's Associate Administrator, and the new address of the Program Office; clarifies that no payments are authorized for fees or costs of personal representatives, including those of attorneys; and corrects a typographical error in § 102.83(c) to make clear that the

Secretary determines the timeframe for submission of required documentation.

DATES: The interim final rule, published on December 16, 2003, was effective on that date, and is adopted as the final rule with an amendment effective May 24, 2006.

FOR FURTHER INFORMATION CONTACT: Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, (301) 443–2330.

SUPPLEMENTARY INFORMATION:

Background

The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Pub. L. 108–20, 117 Stat. 638, directed the Secretary of Health and Human Services (the Secretary) to establish the Program. Secondary to other payers, the Program provides medical, lost employment income, and death benefits for eligible individuals who sustained covered injuries as a result of receiving smallpox vaccine or other covered countermeasures, or as a result of accidental exposure to vaccinia. Congress appropriated \$42 million in fiscal year (FY) 2003 for the administration of, and payment of benefits under, the Program. The Consolidated Appropriations Act of 2005 reduced this amount by \$20 million. The Departments of Labor, Health and Human Services and Education and Related Agencies Appropriations Act, 2006 (Pub. L. 109–149) further reduced the Program's appropriation by \$10 million to a total of \$12 million. Section 220 of the Appropriations Act of 2006 (Pub. L. 109–149) further reduced the Program's appropriation by \$10 million to a total of \$12 million.

Individuals who receive a smallpox vaccination under a Department of Health and Human Services (HHS), State, or local emergency response plan approved by HHS within the time period described in the Secretary's Declaration, and who sustain a covered injury, may be eligible for benefits under SEPPA. Individuals who contracted vaccinia through contact with such individuals or other eligible vaccinia contacts and who sustain a covered injury may also be eligible for benefits. In the case of death resulting directly from receipt of the smallpox vaccine or exposure to vaccinia by eligible individuals, certain of their survivors may be considered for death benefits. If an eligible individual who sustained a covered injury dies from another cause before payment of benefits has been made under the