Oklahoma

The statutory provisions include:

Oklahoma Hazardous Waste Management Act, as amended, 27A Oklahoma Statute 1997 Edition, Sections 2–7–103, 2–7–108(A), 2–7–108(B)(1), 2–7–108(B)(3), 2–7–108(C), 2–7–110(B), 2–7–110(C), 2–7–111(A), 2–7–111(B) (except the last sentence and the phrase, ''recycling'' in the first sentence), 2–7–111(C)(2)(a) (except the phrase ''Except as provided in subparagraph b of this paragraph'' and the word ''recycling'' in the first sentence), 2–7–111(D), 2–7–111(E) (except the word ''recycling'' in the first sentence), 2–7–112, 2–7–116(B) through 2–7–116(F), 2–7–116(H)(2), 2–7–118(A), 2–7–124, 2–7–125, 2–7–127 and 2–10–301(G).

Copies of the Oklahoma statutes that are incorporated by reference are available from West Publishing Company, 610 Opperman Drive, PO Box 64526, St. Paul, Minnesota 55164–0526.

The regulatory provisions include:

The Oklahoma Administrative Code, Title 252, Chapter 205, effective June 12, 2000: Subchapter 1, Sections 252:205–1–1(a), 252:205–1–1(c) introductory paragraph, 252:205–1–1(c)(1), 252:205–1–2 introductory paragraph, 252:205–1–2 ''OHWMA'', 252:205–1–2 ''Post-closure permit'', 252:205–1–3(c); Subchapter 3, Sections 252:205–3–1, 252:205–3–2(a)(2), 252:205–3–2(b)–(m), 252:205–3–4, 252:205–3–5 and 252:205–3–6; Subchapter 5, Sections 252:205–5–1 (except 252:205–5–1(4)), 252:205–5–2 through 252:205–5–5; Subchapter 7, Sections 252:205–7–1 through 252:205–7–3 and 252:205–7–4 (except the phrase ''or in accordance with 252:205–15–1(d)); Subchapter 9 (except 252:205–9–5 and 252:205–9–6); Subchapter 11, 252:205–11–1(a) (except the word ''recycling''), 252:205–11–1(b) through 252:205–11–1(e) and 252:205–11–2; and Subchapter 13, Sections 252:205–13–1(a)—(e).

Copies of the Oklahoma regulations that are incorporated by reference can be obtained from The Oklahoma Register, Office of Administrative Rules, Secretary of State, 101 State Capitol, Oklahoma City, Oklahoma 73105.

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[FR Doc. 03–21592 Filed 8–26–03; 8:45 am]

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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, HHS.

ACTION: Interim Final Rule.

SUMMARY: The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Public Law 108–20, 117 Stat. 638, authorized the Secretary of Health and Human Services (the Secretary), through the establishment of the Smallpox Vaccine Injury Compensation Program (the Program), to provide benefits and/or compensation to certain persons who have sustained injuries as a result of the administration of smallpox covered countermeasures (including the smallpox vaccine) or as a result of vaccinia contracted through accidental vaccinia inoculations.

The SEPPA directed the Secretary to establish, by interim final rule, 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 manifest in order for such presumption to apply. As mandated by law, the Secretary is establishing such a Smallpox (Vaccinia) Vaccine Injury Table (the Table) through this interim final rule. The Secretary is also establishing a set of Table Definitions and Requirements, which define the terms and conditions included on the Table and are to be read in conjunction with the Table.

The Secretary is seeking public comment on the Table established through this interim final rule. At a later date, the Secretary will publish a companion final rule setting forth the administrative implementation of the Program. The public will then be afforded an additional opportunity to comment on the procedures set forth therein.

DATES: This regulation is effective on August 27, 2003. Written comments must be submitted on or before October 27, 2003. The Secretary will consider the comments received and will decide whether to amend the Table based upon such comments.

ADDRESSES: All written comments concerning this interim final rule should be submitted to the Director, Smallpox Vaccine Injury Compensation Program, Office of Special Programs, Health Resources and Services Administration, Parklawn Building, Room 16C–17, 5600 Fishers Lane, Rockville, Maryland 20857. Express and courier mail should be sent to Smallpox Vaccine Injury Compensation Program, Office of Special Programs, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, Maryland 20814. Electronic comments should be sent to *smallpox@hrsa.gov.* Comments received will be available for public inspection at the Office of Special Programs, Health Resources and Services Administration, 4350 East West Highway, 10th Floor, Bethesda, Maryland 20814, between the hours of 8:30 a.m. and 5 p.m. on Federal Government work days.

FOR FURTHER INFORMATION CONTACT: Dr. Vito Caserta, telephone (301) 443–4956. This is not a toll-free number. Electronic inquiries should be sent to *smallpox@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background

Prior to its eradication, smallpox (variola) was a serious illness that manifested either as outbreaks of variola major with death rates of greater than 20 percent or variola minor with death rates approaching 1 percent. Those who survived were frequently left with significant disabilities, such as blindness. Smallpox (vaccinia) vaccine (referred to in this rule as the ''smallpox vaccine'') was an essential tool for the successful global eradication of smallpox (variola), announced by the World Health Organization in 1980. Despite such eradication, concern exists that terrorists may have access to the smallpox (variola) virus (referred to in this rule as the ''smallpox virus'').

On December 13, 2002, the President announced a plan to protect the population of the United States against the threat of a possible smallpox attack. This plan was based on heightened concerns, in the wake of the attacks of September and October 2001, that terrorists may have access to the smallpox virus and may attempt to use it against the population of the United States and government facilities abroad. Under this plan, which the Secretary is actively working to implement, State and local governments have formed volunteer smallpox response teams that will be prepared to provide critical services to the population of the United

States in the event of a smallpox virus attack.

In furtherance of the President's plan, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 24, 2003 (68 FR 4212). In this Declaration, the Secretary declared that ''a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified * * * for prevention or treatment of smallpox [(virus infection)] or control or treatment of adverse events related to smallpox vaccination, to [specified] categories of individuals. * * *'' The specific ''covered countermeasures'' described in the Declaration are smallpox vaccines, cidofovir and derivatives thereof, and Vaccinia Immune Globulin. The categories of persons to whom the Secretary recommended the administration of such covered countermeasures, on a voluntary basis, included certain health care workers, members of smallpox response teams identified by State or local government entities or the Department of Health and Human Services, certain public safety personnel, and certain personnel associated with certain Federal facilities abroad. The Secretary recommended that such persons volunteer to receive the smallpox vaccine in order to ensure that critical personnel would be able to mobilize immediately and provide critical services to the population of the United States in the event of a smallpox virus attack. The Secretary's Declaration became effective on January 24, 2003, and will remain effective until January 23, 2004, unless the Secretary extends or shortens the effective period of the Declaration by amendment.

The smallpox vaccine contains a live vaccinia virus that induces immunity to smallpox infection, but does not lead to variola infection or disease. Vaccinia virus is an orthopox type virus that is different from, but related to, the smallpox virus. Different strains of vaccinia have been used in the development of smallpox vaccines throughout the world, with some strains causing more injuries than other strains. The New York City Board of Health strain, ''the NYCBH strain,'' is the only strain currently used in vaccines administered in the United States. The NYCBH strain was selected for use in such vaccines because it has shown itself to be both relatively safe and effective when compared to other vaccinia strains. Nevertheless, the routine use of smallpox vaccination in the United States and several other countries, irrespective of the strain used, was discontinued prior to the certification of global eradication of smallpox. This was due to the relatively high complication rate observed with the smallpox vaccine, in addition to the lower risk of importation of smallpox with the increasing success of the global eradication program.

Because the vaccinia virus in the smallpox vaccine is live, it can be transmitted to other parts of the body of the vaccine recipient, *e.g.*, by touching a vaccination site before it has healed and then touching another part of the recipient's body (self-inoculation), or to another person, *e.g.*, by touching a vaccination site in a recipient before it has healed and then touching another person (accidental person-to-person inoculation). For purposes of this rule, the term ''vaccination'' refers to the administration and receipt of the smallpox vaccine and not through contact. Likewise, for purposes of this rule, the term ''inoculation'' is meant to refer to transmission of and subsequent infection with the vaccinia virus through a means other than smallpox vaccination, as described above.

Even though several studies documented the rate of serious complications after receipt of the smallpox vaccine during the 1960s and 1970s, these rates may be higher today as more individuals are immunocompromised, which has the same meaning for purposes of this regulation as immunosuppressed or immunodeficient. Furthermore, persons receiving primary smallpox vaccination under a smallpox emergency response plan will be doing so as adults. The earlier studies also primarily sought information only on what was known already to be caused by the smallpox vaccine. Unrecognized adverse reactions that may become more clearly evident with improved surveillance may not have been studied in the past.

The SEPPA authorized the Secretary to establish and implement the Smallpox Vaccine Injury Compensation Program. Under the Program, certain persons may receive benefits and/or compensation for covered injuries, described below, sustained as a result of such vaccination or accidental vaccinia inoculation. Specifically, SEPPA authorizes the Secretary to make available such benefits and/or compensation to two categories of persons who sustain covered injuries, provided they meet other legal requirements, *e.g.*, filing deadlines. The first category, described as ''recipients,'' includes certain persons who volunteer for and are selected to be a member of a smallpox emergency response plan and are vaccinated with smallpox vaccine. In the event that recipients sustain covered injuries as the result of the administration of the smallpox vaccine or other covered countermeasures listed in the Secretary's Declaration, they may be entitled to benefits and/or compensation under the Program. The second category, described as ''contacts,'' includes certain persons who sustained covered injuries as the result of vaccinia contracted through accidental vaccinia inoculation through contact with categories of recipients described in the SEPPA or the contacts of such recipients. In addition, survivors of deceased recipients or contacts may be eligible for benefits and/or compensation under the Program in certain circumstances. Persons who do not meet the criteria for one of these categories (*e.g.*, individuals who receive the smallpox vaccine, but not as part of an approved smallpox emergency response plan) will not be entitled to benefits.

In order to obtain benefits and/or compensation under the Program, eligible individuals in these categories must file a request with the Program and demonstrate to the Secretary in their requests that applicable eligibility, benefits, and compensation criteria are satisfied. Persons filing such requests with the Program are described as requesters. The benefits and compensation available under the Program include compensation for medical care, lost employment income, and a death benefit for certain survivors of persons who died as the result of a covered injury. A requester's entitlement to such benefits and compensation will vary depending upon the nature of the requester's condition, the requester's particular personal circumstances, *e.g.*, whether the requester has insurance coverage, and the completeness of the request and accompanying documentation.

Among the criteria that must be satisfied in order for a person to be entitled to such benefits and/or compensation is the requirement that a person sustained a ''covered injury'' as the result of the administration of a covered countermeasure or as the result of an accidental vaccinia inoculation. A requester can demonstrate that such a covered injury, an injury either proven or presumed to be caused by the vaccinia virus contained in the smallpox vaccine or transmitted through accidental vaccinia inoculation and meeting all applicable requirements, occurred through two alternative mechanisms. First, in accordance with the SEPPA, a recipient or contact shall be presumed to have sustained a covered injury as the result of the

administration of or exposure to the smallpox vaccine if the requester submits sufficient documentation demonstrating that the event is included on an injury table (*i.e.*, the Table) created by the Secretary with the onset of the first symptom or manifestation within the time interval specified on the Table. For this reason, if an otherwise eligible person sustained an injury listed on the Table in the time interval listed on the Table, the Secretary will presume, solely for purposes of the Program, that this event was caused by the smallpox vaccine. Such a requester need not actually demonstrate that the vaccine or the vaccinia contracted from accidental vaccinia inoculation caused the underlying injury, only that an injury listed on the Table was sustained with the first manifestation within the time interval listed on the Table.

This presumption is not conclusive, however. The Secretary may determine, based on his review of the relevant evidence, that an injury meeting the Table requirements was most likely caused by other factors and was not caused by the smallpox vaccine or exposure to vaccinia in contact cases. In these circumstances, the Table presumption could be rebutted, and the requester may not be entitled to benefits and/or compensation under the Program.

The alternative mechanism to demonstrate that a covered injury was sustained is available when a requester cannot demonstrate that a Table injury occurred within the time interval listed on the Table. In such circumstances, the requester must submit sufficient documentation showing that the smallpox vaccine or other covered countermeasures, or the vaccinia contracted from accidental vaccinia inoculation, actually caused the injury that is the basis for the request. In evaluating such claims, the Secretary will employ a preponderance of the evidence standard, taking into consideration all relevant medical and scientific evidence, including all relevant medical records.

As authorized and mandated under the SEPPA, the Secretary is herein establishing, at 42 CFR 102.21, a Table that identifies injuries, *i.e.*, illnesses, disabilities, injuries, or conditions, referred to as ''Table injuries,'' that shall be presumed to result from the administration of or exposure to the smallpox vaccine, as well as the time interval in which the first symptom or manifestation of each such injury must manifest in order for this presumption to apply. The Secretary is further including Table Definitions and Requirements, set forth in 42 CFR 102.21(b), which define the terms and conditions included in the Table and set forth the requirements necessary to establish Table injuries. As such, the Table Definitions and Requirements are considered a part of the Table.

At this time, the Secretary is seeking public comment on the Table established through this interim final rule. The Secretary will solicit comments on other matters pertaining to the implementation of the Program in the future, when the Secretary publishes a companion rule detailing the policies and procedures for the implementation of the Smallpox Vaccine Injury Compensation Program.

Summary of Regulation

Smallpox (Vaccinia) Vaccine Injury Table

This interim final rule establishes the Table, which includes the covered injuries for the smallpox vaccine and the relevant time intervals for ''recipient requests'' (requests concerning injuries in relation to the administration of the smallpox vaccine) and ''contact requests'' (requests concerning injuries in relation to vaccinia contracted through accidental vaccinia inoculation from another person). In order to obtain the presumption of causation afforded by the Table, a requester filing a recipient request must demonstrate that the onset of the recipient's first symptom or manifestation of an injury listed on the Table occurred within the timeframe listed on the Table in relation to the administration of the smallpox vaccine. Likewise, in order to obtain the Table presumption of causation, a requester filing a contact request must demonstrate that the onset of the contact's first symptom or manifestation of the injury listed on the Table occurred within the time interval listed on the Table in relation to any date in the exposure period.

A contact may be exposed to vaccinia on any date in the exposure period, which is the span of time during which transmission of vaccinia virus from a vaccine recipient or another contact shedding vaccinia can occur. The risk of exposure from viral shedding from a recipient or contact is generally considered no longer to exist when the scab from each vaccinial lesion spontaneously falls off, which usually occurs approximately three weeks after vaccination or inoculation in a healthy person and may be considerably longer in the immunocompromised or those experiencing injuries such as eczema vaccinatum.

The time intervals listed on the Table for recipients reflect the quantity of time between vaccination and the onset of the first symptom or manifestation of the Table injury. For contacts, because the exact time the vaccinia virus is transmitted cannot generally be pinpointed, the time intervals listed on the Table reflect a comparable quantity of time between exposure to vaccinia (i.e. any point in the exposure period) and the onset of the first symptom or manifestation of the Table injury.

The injuries included on the Table, as well as the time intervals set forth for both recipients and contacts, represent the Secretary's best effort to include a comprehensive listing of injuries believed to be causally related to the smallpox vaccine. The Table is meant to represent the known NYCBH strain injuries where credible medical evidence suggests that the smallpox vaccine has a causal role in the injury and the time intervals in which such known events first manifest in relation to the administration of the smallpox vaccine, or the exposure to vaccinia in contact cases. However, the Table covers all smallpox vaccines administered under the Secretary's Declaration. With future generations of smallpox vaccines, the Secretary may need to amend the Table to fit the injury profile of the new vaccine.

Although the occurrence of many of the injuries included on the Table appears to be exceedingly rare, the Secretary is including such injuries on the Table in order to ensure that people who are otherwise eligible for benefits and/or compensation under the Program will receive the Table's presumption of causation in those instances in which the credible medical literature persuasively suggests a causal relationship between the smallpox vaccine and the injury. The Table presumption can be rebutted if the Secretary determines, based on a review of the relevant evidence, that an injury meeting the Table requirements was not caused by the smallpox vaccine or exposure to vaccinia in contact cases.

The Secretary is aware of anecdotal reports of ischemic heart disease, such as angina pectoris or myocardial infarction (heart attacks) occurring in a few individuals following receipt of the smallpox vaccine. The Secretary has included vaccinia-related myocarditis, pericarditis, and myopericarditis as Table injuries but, at this time, there is no clear scientific evidence to support including ischemic heart disease as a separate Table injury.

Nevertheless, where a requester can demonstrate that an ischemic heart disease following a covered Table injury was likely caused by, or was a health complication (i.e., sequela) of, the Table

injury, we expect that the requester will be eligible for benefits associated with the ischemic heart disease.

Should sufficient scientific evidence be forthcoming that ischemic heart disease (absent these Table conditions) is caused by the vaccine, the Secretary would amend the Table (see discussion below), with retroactive effect, to include this condition too. Furthermore, even absent a Table injury for ischemic heart disease, requesters may provide sufficient evidence of causation in fact for this injury, which might also lead to Program benefits.

The Secretary will provide further information in the forthcoming companion regulation as to how he will determine whether an event was caused by, or was a health complication of, a covered injury.

In addition to specific injuries, the Table includes a category for any death resulting from an injury included on the Table in which the injury arose within the time interval set forth on the Table. No time interval is specified for the category of death. Therefore, so long as the Secretary determines that the death resulted from an injury meeting the Table requirements, the death can occur at any time subsequent to the injury and not necessarily in the time interval set forth on the Table.

Table Definitions and Requirements

The Table's Definitions and Requirements, set forth in 42 CFR 102.53(b), define and describe the scope of the terms included on the Table. As such, the listings included on the Table are to be read in conjunction with the Definitions and Requirements. For each Table injury, the Table Definitions and Requirements must be satisfied.

By law, requesters will be required to provide documentation showing that they meet other eligibility criteria, separate from the Table, in order to demonstrate eligibility to receive benefits and/or compensation under the Program. For example, each requester filing a contact request is required by law to demonstrate to the Secretary that the contact contracted vaccinia through accidental vaccinia inoculation during the effective dates of the Secretary's Declaration, or up to 30 days thereafter. This requirement applies to all contact requests filed, regardless of whether the injury in question is included on the Table. For this reason, the requirement that a requester with a contact request demonstrate that the contact contracted vaccinia within the time interval specified by law is not incorporated into the Table. The companion regulations that the Secretary will issue in the future will provide detailed information concerning this requirement and other requirements that requesters must satisfy beyond those that pertain exclusively to injuries included on the Table.

Requests Based on Non-Table Injuries

A requester may be eligible to receive benefits and/or compensation available through the Program even if the underlying injury is not included on the Table, as defined through the Definitions and Requirements, or did not occur within the time-frame included on the Table. Because such requesters will not be afforded the presumption of causation given to requesters who establish Table injuries, requesters filing requests based on non-Table injuries must submit documentation that demonstrates to the Secretary that the injury underlying the request was actually caused by the administration of the covered countermeasure, or by vaccinia through accidental vaccinia inoculation in contact requests. The Secretary will give full and fair review of all such requests.

Medical evidence available concerning a possible causal link between the vaccinia virus and particular conditions may not be sufficient for the Secretary to add such conditions to the Table. However, such evidence together with medical documentation introduced by particular requesters may be sufficient for requesters with such conditions to persuade the Secretary that the vaccinia virus from vaccination or inoculation was a significant factor in causing the condition. For example, medical literature suggests that the vaccinia virus has caused acute vaccinial arthritis (VA) or vaccinial osteomyelitis (VO) in isolated instances. As a result, requesters with such conditions may be entitled to compensation even when such conditions are not included on the Table. In order to demonstrate that a particular person's condition was caused by the vaccinia virus through vaccination or inoculation, requesters must provide evidence demonstrating such a link, *e.g.*, evidence that the vaccinia virus was present in an infected joint in a case of alleged VA or in an osteomyelitis in a case of alleged VO. Such evidence may persuade the Secretary to determine that the person sustained a covered, albeit a non-Table, injury. Likewise, persons in whom a malignant melanoma (MM), basal cell carcinoma (BCC), or squamous cell carcinoma (SCC) originated with the first manifestation in a vaccination or inoculation scar may be able to demonstrate to the Secretary that the vaccinia virus caused the MM, BCC, or SCC. This is consistent with the rare cases in the medical literature in which a causal link has been suggested between the vaccinia virus and such skin tumors, *e.g.*, persons who developed new tumors, *i.e.*, MM, BCC, or SCC (as the first manifestation of each tumor) in separate vaccinial scars from separate vaccinations given years apart.

To decide whether benefits and/or compensation under the Program are available in relation to a request that does not concern a Table injury, the Secretary will review the materials provided in each case. In reviewing these requests, the Secretary will employ a preponderance of the evidence standard, taking into consideration relevant medical and scientific evidence. The Secretary will provide further information concerning such requests when he publishes the companion final rule setting forth the administrative implementation of the Program.

No Table for Other Non-Vaccine Covered Countermeasures

The Secretary was statutorily directed to establish a Table identifying injuries presumed to result from the administration of or exposure to the smallpox vaccine. The SEPPA did not direct the Secretary to establish such a Table in relation to injuries presumed to result from the administration of other covered countermeasures. Nonetheless, certain requesters may still be entitled to benefits and/or compensation in relation to injuries that resulted from covered countermeasures other than the smallpox vaccine, *i.e.*, Vaccinia Immune Globulin, cidofovir and derivatives thereof. Requesters filing requests in relation to such injuries are not afforded the presumption of causation given to requesters who have sustained Table injuries. For this reason, a requester filing a request in relation to such non-vaccine covered countermeasures, as with any non-Table request, must demonstrate to the Secretary that the administration of the covered countermeasure actually caused an injury for which benefits and/or compensation may be available under the Program.

Amendments to Table

In accordance with Section 263(a)(2) of the Public Health Service Act (PHS Act), as established by SEPPA, the Secretary is authorized to amend by regulation the Table established in this interim final rule. The Secretary intends to monitor injuries in relation to covered countermeasures, including the smallpox vaccine. Based upon the best scientific evidence available, the

Secretary will amend the Table to add new injuries, to modify the governing time intervals, or to modify Table definitions, when the evidence supports doing so. Such amendments will apply to pending requests and to requests filed after the amendments take effect. Requesters who become eligible with respect to an injury on the Table as the result of such an amendment may file a request based on the amendment within the time period prescribed by law.

Justification for Omitting Notice of Proposed Rulemaking and for Waiver of Delayed Effective Date

Through the enactment by the SEPPA of Section 263(a)(1) of the PHS Act, the Secretary was directed to establish by interim final rule a table identifying injuries 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 such injury must manifest in order for such presumption to apply. In accordance with that statutory directive, the Secretary is herein establishing such a Table, including Definitions and Requirements. As noted earlier, the establishment of this Table by interim final rule was authorized by statute.

The Secretary has further determined, under 5 U.S.C. 553(b), that it is contrary to the public interest to follow the notice of proposed rulemaking procedures before issuance of these regulations, because such a process might delay the continuing implementation of the President's plan to protect the population of the United States against the threat of a smallpox (variola) attack. A significant element of this plan, which is also an important priority of the Secretary, is the increased voluntary participation of persons in smallpox emergency response plans throughout the Nation, which includes voluntary immunization with the smallpox vaccine. The companion regulation, which will serve to implement the Program, will be issued after this regulation is in effect. The sooner that this regulation becomes effective, the sooner potential requesters will be able to assess their eligibility to recover benefits and/or compensation from the Program and to recover such benefits and/or compensation, if eligible. For the same reasons, the Secretary has determined that there is good cause to waive a delay in the rule's effective date.

As noted above, comments will be accepted at the above listed address for a period of 60 days following the publication of this rule.

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 (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.

Congress has found it necessary to appropriate $42,000,000 for the administration of, and payment of the Program. Because any resources required to implement the regulatory requirements imposed by the SEPPA are not required by virtue of the establishment of a Table, and because the Secretary will conduct an independent analysis concerning any burdens associated with the implementation of the Program when the Secretary publishes the companion regulations setting forth the Program's administrative implementation, the Secretary has determined that no resources are required to implement the provisions included in this regulation. Therefore, in accordance with the RFA of 1980, and the Small Business Regulatory Enforcement Fairness 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 proposed interim 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. The Secretary has determined that the proposed interim 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 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.''

On the basis of family well-being, the provisions of this interim final rule will not 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.

Impact of the New Rule

In this interim final rule, the Secretary establishes a Smallpox (Vaccinia) Vaccine Injury Table identifying injuries that shall be presumed to result from the administration of or exposure to the smallpox vaccine, and the time interval in which the onset of the first symptom or manifestation of each such injury must manifest in order for such presumption to apply. The Secretary also is providing Table Definitions and Requirements. This interim final rule is based upon legal authority. This interim final rule will have the effect of affording certain persons a presumption that particular injuries were sustained as the result of the administration of or exposure to the smallpox vaccine. Because the Table establishes a presumption of causation, it relieves requesters of the burden of demonstrating causation for covered events.

Paperwork Reduction Act of 1995, as Amended

This interim final rule has no information collection requirements.

List of Subjects in 42 CFR Part 102

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

Dated: July 18, 2003.

Elizabeth M. Duke,

Administrator, Health Resources and Services Administration.

Approved: July 22, 2003.

Tommy G. Thompson,

Secretary.

■ For the reasons stated above, the Department of Health and Human Services adds to Subchapter J of Chapter I of Title 42 CFR, a new part 102 to read as follows:

PART 102—SMALLPOX COMPENSATION PROGRAM

Sec.

Authority: Sec. 215 of the Public Health Service Act (42 U.S.C. 216); sec. 263 of the PHS Act, as amended, Public Law No. 108–20, 117 Stat. 638.

§102.21 Smallpox (Vaccinia) Vaccine Injury Table.

(a) SMALLPOX (VACCINIA) VACCINE INJURY TABLE

Injury (illness, disability, injury, or condition)	Time interval for first symptom or manifestation of onset of injury after: (1) administration of smallpox (vaccinia) vaccine in recipients (R); or (2) exposure to vaccinia in contacts (C)
1. Significant Local Skin Reaction	R or C: 1–21 days.
2. Stevens-Johnson Syndrome	R or C: 1–21 days.
3. Inadvertent Inoculation	R or C: 1–21 days.
4. Generalized Vaccinia	R or C: 1–21 days.
5. Eczema Vaccinatum	R or C: 1–21 days.
6. Progressive Vaccinia	R or C: 1–21 days.
7. Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis	R or C: 1–21 days.
8. Fetal Vaccinia	Maternal R or C: any time in gestation until 7 days after birth.
9. Secondary Infection	R or C: 0–30 days.
10. Anaphylaxis or Anaphylactic Shock	R: 0–4 hours. C: Not Covered.
11. Vaccinial Myocarditis, Pericarditis, or Myopericarditis	R or C: 1–21 days.
12. Death resulting from an injury referred to above in which the injury arose within the time interval referred to above (except as specifically provided in specified paragraph (b) of this section).	R or C: No time interval specified.

(b) *Table Definitions and Requirements*

The Table Definitions that follow shall apply to, define and describe the scope of, and be read in conjunction with paragraph (a) of this section.

(1) *Significant local skin reaction.*—(i) *Definition.* Significant local skin reaction is, for purposes of the Table, an unexpected and extreme response at the vaccination or inoculation site that results in a significant scar that is serious enough to require surgical intervention. The onset of this injury is the initial skin lesion at the vaccination or inoculation site that generally occurs with smallpox vaccinations or inoculations. Minor scarring or minor local reactions do not constitute a Table injury. Even a robust take, defined as an area of redness at the vaccination site that exceeds 7.5 cm in diameter with associated swelling, warmth and pain, in general is considered an expected response to the vaccination or inoculation. A robust take does not in itself constitute a Table injury, even when the redness and swelling involves the entire upper arm with associated enlargement and tenderness of the glands (lymph nodes) in the underarm (axilla).

(ii) *Table requirements.* A Table injury for a significant local skin reaction in a recipient or contact requires sufficient evidence in the medical records of the occurrence of a significant local skin reaction at the vaccination or inoculation site and a permanent, disfiguring scar that resulted from the significant local skin reaction. The scar must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*, contracture) deformity and such surgery must be included in the treatment plan documented in the medical records.

(2) *Stevens-Johnson Syndrome (SJS).*—(i) *Definition.* SJS (sometimes called erythema multiforme major) is an acute hypersensitivity reaction that affects skin, mucous membranes, and sometimes internal organs (systemic toxicity). For purposes of the Table, both skin and mucous membrane rash or lesions must be present and the rash or lesions may not cover less than ten percent of body surface area. In SJS, mucosal involvement generally predominates. Mucosal lesions generally occur at more than one location and manifest as painful lesions in sites such as the mouth or eyes. Skin rash or lesions in SJS usually consist of red raised areas (erythematous macules), blisters, and ulcerations.

(ii) *Table requirements.* A Table injury for SJS in a recipient or contact requires sufficient evidence in the medical records of the occurrence of SJS. The SJS, or related complications, must be of sufficient severity to require inpatient hospitalization.

(3) *Inadvertent Inoculation (II).*—(i) *Definition.* II is the spread of vaccinia virus from an existing vaccination or inoculation site to a second location usually by scratching the vaccination or inoculation site and subsequently spreading the virus, which produces a new vaccinial lesion on the same person. Alternatively, II is the spread of vaccinia virus from an existing vaccination or inoculation site to another person usually by scratching an existing vaccination or inoculation site and subsequently spreading the virus, resulting in a contact case.

(ii) *Table requirements.* A Table injury for II in a recipient or contact requires sufficient evidence in the medical records of the occurrence of II and the occurrence of one of the following:

(A) Eye lesions, *e.g.*, vaccinial keratitis or vaccinial blepharitis, that resulted from II and that led to a permanent sequela, *e.g.*, decrease in visual acuity;

(B) Permanent and disfiguring scar(s) that resulted from II. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*,

contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(C) Acute II or related complications of sufficient severity to require inpatient hospitalization.

(4) *Generalized Vaccinia (GV).*—(i) *Definition.* GV is a vaccinial infection that occurs from the spread of vaccinia from an existing vaccination or inoculation site to otherwise normal skin, resulting in multiple new areas of vaccinial rash or lesions. The vaccinia is believed to be spread through the blood. The rash or lesions are characterized by multiple blisters (vesicles or pustules) that generally evolve in a similar sequence or manner as the original vaccination or inoculation site.

(ii) *Table requirements.* A Table injury for GV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of GV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from GV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*, contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute GV or related complications of sufficient severity to require inpatient hospitalization.

(5) *Eczema Vaccinatum (EV)*—(i) *Definition.* EV is the transmission or the spread of vaccinia virus from a vaccination or inoculation site to skin that has been affected by, or is currently affected with, eczema or atopic dermatitis. EV is characterized by lesions that include multiple blisters (vesicles or pustules), which generally evolve in a similar sequence or manner as the original vaccination or inoculation site. The lesions may come together to form larger lesions. Lesions may also spread to patches of skin that have never been involved with eczema or atopic dermatitis. A person with EV may be quite ill with signs and symptoms that involve the whole body (systemic illness), such as fever, malaise, or enlarged glands (lymph nodes).

(ii) *Table requirements.* A Table injury for EV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of EV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from EV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*, contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute EV or related complications of sufficient severity to require inpatient hospitalization.

(6) *Progressive Vaccinia (PV).*—(i) *Definition.* PV is the failure to initiate the healing process in an initial vaccination or inoculation site by 21 days after exposure to vaccinia with progressive ulceration or necrosis at the vaccination or inoculation site leading to a large destructive ulcer. PV is seen in people with an impaired immune system (immunocompromised) and is characterized by a complete or near complete lack of inflammation or absence of inflammatory cells in the dermis of the skin at the vaccination or inoculation site. The diagnosis of PV may be made before 21 days after exposure, especially in a known immunocompromised individual who develops a lesion at the vaccination or inoculation site. PV may spread through the blood to any location in the body. Any person who initiates a significant healing process of the vaccination or inoculation site by 21 days after receipt of the smallpox vaccine or exposure to vaccinia does not have PV.

(ii) *Table requirements.* A Table injury for PV in a recipient or contact requires sufficient evidence in the medical records of the occurrence of PV and the occurrence of one of the following:

(A) Permanent and disfiguring scar(s) that resulted from PV. The scar(s) must be of sufficient severity to require surgical intervention to correct a significant cosmetic (*e.g.*, keloid) or functional (*e.g.*, contracture) deformity and such surgery must be included in the treatment plan documented in the medical records; or

(B) Acute PV or related complications of sufficient severity to require inpatient hospitalization.

(7) *Postvaccinial Encephalopathy, Encephalitis or Encephalomyelitis (PVEM).*—(i) *Definition.* PVEM is, for the purposes of the Table, an autoimmune central nervous system injury. In rare cases, the vaccinia virus is isolated from the central nervous system. Manifestations usually occur abruptly and may include fever, vomiting, loss of appetite (anorexia), headache, general malaise, impaired consciousness, confusion, disorientation, delirium, drowsiness, seizures, language difficulties (aphasia), coma, muscular incoordination (ataxia), urinary incontinence, urinary retention, and clinical signs consistent with inflammation of the spinal cord (myelitis) such as paralysis or meningismus. Long term central nervous system impairments such as paralysis, seizure disorders, or developmental delays are known to occur as sequelae of the acute PVEM. No clinical criteria, radiographic findings, or laboratory tests are specific for the diagnosis of PVEM.

(ii) *Table Requirements.* A Table injury for PVEM in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute PVEM. The acute PVEM or related complications must be of sufficient severity to require inpatient hospitalization.

(8) *Fetal Vaccinia (FV).*—(i) *Definition.* FV is an intrauterine vaccinial infection subsequent to vaccinia vaccination or inoculation of the mother that results from the placental transmission of the vaccinia virus during any time in the pregnancy. FV manifests as multiple skin lesions or organ involvement and may result in significant scarring or death. FV skin lesions are similar to those seen in GV or PV and the lesions may come together to form larger lesions. Congenital malformations, other than those described above, are not Table injuries.

(ii) *Table requirements.* A Table injury for FV requires sufficient evidence in the medical records of the occurrence of the FV. The occurrence of the FV or related complications must be of sufficient severity to require inpatient hospitalization or result in permanent and disfiguring scar(s). In addition, a Table injury for FV requires one of the following:

(A) A maternal history of vaccinial vaccination or inoculation, with the occurrence of vaccinial skin or mucous membrane lesions within the incubation period for vaccinia during the pregnancy in a maternal recipient or contact; or

(B) Isolation of vaccinia from intrauterine or neonatal tissue.

(9) *Secondary Infection (SI).*—(i) *Definition.* SI is, for purposes of the Table, a non-vaccinial bacterial, fungal, or viral infection at the site of a vaccinial skin or mucous membrane lesion. SI occurs because the blister formation or ulceration that is part of the normal progression of a vaccinial skin or mucous membrane lesion disrupts the surface of the skin or mucous membrane, allowing potential germs to invade and infect the vaccinial skin or mucous membrane lesion leading to significant illness requiring hospitalization.

(ii) *Table requirements.* A Table injury for SI in a recipient or contact

requires sufficient evidence in the medical records of the occurrence of SI. The acute SI or related complications must be of sufficient severity to require inpatient hospitalization.

(10) *Anaphylaxis or Anaphylactic shock.*—(i) *Definition.* Anaphylaxis or anaphylactic shock is, for purposes of the Table, as an acute, severe, and potentially lethal systemic allergic reaction to a component of the smallpox vaccine.

(ii) *Table requirements.* A Table injury for anaphylaxis or anaphylactic shock in a recipient requires sufficient evidence in the medical records of the occurrence of an acute anaphylaxis or anaphylactic shock. The anaphylaxis or anaphylactic shock must be of sufficient severity to require inpatient hospitalization. Anaphylaxis or anaphylactic shock is not a Table injury for contacts.

(11) *Vaccinial Myocarditis, Pericarditis, or Myopericarditis (MP).*—(i) *Definition.* MP is, for purposes of the Table, vaccinial myocarditis, pericarditis, or myopericarditis. Myocarditis is defined as an inflammation of the heart muscle (myocardium). Pericarditis is defined as an inflammation of the covering of the heart (pericardium). Myopericarditis is defined as an inflammation of both the heart muscle and its covering. The inflammation associated with MP may range in severity from very mild (subclinical) to life threatening. In many mild cases, myocarditis is diagnosed solely by transient electrocardiographic (EKG) abnormalities (*e.g.*, ST segment and T wave changes), increased cardiac enzymes, or mild echocardiographic abnormalities. Arrhythmias, abnormal heart sounds, heart failure, and death may occur in more severe cases. Pericarditis generally manifests with chest pain, abnormal heart sounds (pericardial friction rub), EKG abnormalities (*e.g.*, ST segment and T wave changes), and/or increased fluid accumulation around the heart.

(ii) *Table requirements.* A Table injury for MP in a recipient or contact requires sufficient evidence in the medical records of the occurrence of acute MP. The acute MP (or related complications) must be of sufficient severity to require inpatient hospitalization. A death resulting from MP requires sufficient microscopic (histopathologic) evidence of MP or its sequela in heart tissue.

(c) *Glossary for Purposes of This Section*

(1) *Blister or vesicle* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of fluid.

(2) *Contact* means a person who developed a vaccinial lesion or infection through inoculation (and not vaccination).

(3) *Exposure period* means the span of time during which vaccinia virus can be transmitted from a vaccine recipient shedding vaccinia or through a contact case shedding vaccinia.

(4) *Inoculation* means transmission of and infection with the vaccinia virus through a means other than smallpox vaccination. Spread (inoculation) of vaccinia virus may occur in two ways: either self-inoculation in which the vaccinia virus is spread from the vaccinial lesion at the vaccination site to one or more areas on the same person or person-to-person inoculation when the vaccinia virus is spread to another person, a contact.

(5) *Inoculation site* means the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination.

(6) *Lesion* means a pathologic change.

(7) *Pustule* means a circumscribed, elevated skin or mucous membrane lesion containing an accumulation of white blood cells.

(8) *Recipient* means a person to whom the smallpox vaccine was administered.

(9) *Ulceration* means a specific skin or mucous membrane lesion characterized by erosion of the skin or mucous membrane surface.

(10) *Vaccination* means the administration and receipt of the smallpox (vaccinia) vaccine, and not through contact.

(11) *Vaccination* site means the skin surface where the vaccinia virus entered the body through vaccination.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 1

[USCG 2003–15137]

RIN 1625–AA71

Right To Appeal; Director, Great Lakes Pilotage

AGENCY: Coast Guard, DHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: On June 23, 2003, we published a direct final rule that notified the public of the Coast Guard's intent to amend its appellate procedures to provide explicit authority for appeal of decisions or actions taken by the Director, Great Lakes Pilotage. We have not received an adverse comment, or notice of intent to submit an adverse comment, on this rule. Therefore, the rule will go into effect as scheduled.

DATES: The effective date of the direct final rule is confirmed as August 22, 2003.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Tom Lawler, Coast Guard, telephone 202–267–1241. If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Docket Operations, Department of Transportation, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION: On June 23, 2003, we published a direct final rule [68 FR 37091] that notified the public of the Coast Guard's intent to amend its appellate procedures to provide explicit authority for appeal of decisions or actions taken by the Director, Great Lakes Pilotage. We have not received an adverse comment, or notice of intent to submit an adverse comment, on this rule. Therefore, the rule will go into effect as scheduled.

Dated: August 21, 2003.

T.H. Gilmour,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. 03–21966 Filed 8–26–03; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 1 and 25

[IB Docket Nos. 02–34 and 02–54, FCC 03–102]

Satellite Licensing Procedures

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission adopts new satellite licensing procedures, intended to enable the Commission to issue satellite slicenses more quickly. In addition, the Commission eliminates the anti-trafficking rule for satellites, together with new safeguards to protect against speculation. These actions are necessary to expedite provision of satellite services to the public, without allowing satellite license applicants to abuse the Commission's licensing procedures.

DATES: Effective August 27, 2003, except for §§ 25.137(d)(4), 25.164 (c) through