

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 vaccinal 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