

**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, HHS.**ACTION:** Interim final rule.

**SUMMARY:** The Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), authorizes the Secretary of Health and Human Services (the Secretary), to establish the Smallpox Vaccine Injury Compensation Program ("the Program"). This program is designed to provide benefits and/or compensation to certain persons harmed as a direct result of receiving smallpox covered countermeasures, including the smallpox vaccine, or as a direct result of contracting vaccinia through certain accidental exposures. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as the direct result of these injuries.

On August 27, 2003, the Secretary published an interim final rule that set out a Smallpox (Vaccinia) Vaccine Injury Table ("the Table"). The table includes adverse effects (including injuries, disabilities, conditions, and deaths) within specific time periods that shall be presumed to result from the receipt of, or exposure to, the smallpox vaccine. The Secretary will use this table, as well as the procedures set out in this regulation, in deciding whether persons are eligible to receive benefits under the program.

In this interim final rule, the Secretary is setting out the administrative policies, procedures, and requirements governing the program, as authorized by the SEPPA. The Secretary is seeking public comment on this interim final rule.

**DATES:** This regulation is effective on December 16, 2003. Written comments must be submitted on or before February 17, 2004. The Secretary will consider the comments received and will decide whether to amend the current procedures and requirements based on such comments.

**ADDRESSES:** All written comments concerning this interim final rule should be submitted to the Director, Smallpox Vaccine Injury Compensation

Program, Special Programs Bureau, Health Resources and Services Administration, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857. Express and courier mail should be sent to the Director, Smallpox Vaccine Injury Compensation Program, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814. Electronic comments should be sent to [smallpox@hrsa.gov](mailto:smallpox@hrsa.gov). Comments received will be available for public inspection at the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, 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 workdays.

**FOR FURTHER INFORMATION CONTACT:** Paul T. Clark, Director, Smallpox Vaccine Injury Compensation Program, telephone 1-888-496-0338. This is a toll-free number. Electronic inquiries should be sent to [smallpox@hrsa.gov](mailto:smallpox@hrsa.gov). Interested parties may also wish to consult the program's Web site at <http://www.hrsa.gov/smallpoxinjury>.

**SUPPLEMENTARY INFORMATION:****Background**

Before it was eradicated, smallpox (variola) was a serious illness that manifested as outbreaks of either variola major with death rates of greater than 20% or variola minor with death rates of almost 1%. The smallpox (vaccinia) vaccine (referred to in this rule as 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. The smallpox vaccine was an essential tool for the successful global eradication of the smallpox virus, announced by the World Health Organization in 1980. Despite such eradication, concern exists that terrorists may have access to 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 smallpox emergency response plans to facilitate the provision of critical services to the population of the United States in the event of a smallpox virus attack.

To further the President's plan, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 24, 2003 (68 FR 4212). This Declaration was issued pursuant to statutory authority, 42 U.S.C. 233(p)(2)(A), which was enacted by the Homeland Security Act of 2002, Pub. L. 107-296, 116 Stat. 2135. In this Declaration, the Secretary stated that "a potential bioterrorist incident makes it advisable to administer, on a voluntary basis, covered countermeasures specified \* \* \* for prevention or treatment of smallpox 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 its derivatives, 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, certain public safety personnel, other members of smallpox emergency response plans identified by State or local government entities or the Department of Health and Human Services, and certain personnel associated with specific Federal facilities abroad. The Secretary recommended that such persons receive the smallpox vaccine to ensure the immediate mobilization of smallpox emergency response personnel who would 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 that time period by amendment.

Under the Smallpox Vaccine Injury Compensation Program authorized by the SEPPA, certain persons may be entitled to benefits (defined as benefits and/or compensation) for covered injuries, described below, suffered as a direct result of the administration of smallpox covered countermeasures (including the smallpox vaccine) or accidental vaccinia inoculation. Specifically, the SEPPA authorizes the Secretary to make the benefits available to two categories of eligible persons who sustained covered injuries, provided

they meet the legal requirements (*e.g.*, filing deadlines).

The first category, "smallpox vaccine recipients," includes certain persons who volunteer for, and are selected to be members of, a smallpox emergency response plan, are vaccinated with a smallpox vaccine under such a plan, and sustain covered injuries. The second category, vaccinia contacts, includes certain persons who have covered injuries as the direct result of exposure to vaccinia through contact with certain persons who received the smallpox vaccine or with the contacts of such recipients. In addition, if a person in either category dies, his or her survivors or his or her estate may be eligible for selected benefits under this program in certain circumstances.

The benefits available under the program include compensation for medical care, lost employment income, and survivor death benefits. To be considered for program benefits, requesters (*i.e.*, smallpox vaccine recipients, vaccinia contacts, survivors, or the representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts), or persons filing on their behalf as their representatives, must file a Request Form and the documentation required under this regulation to show that they are eligible.

As mandated under the SEPPA, the Secretary is herein, at 42 CFR part 102, establishing the procedures and requirements governing the program. At this time, the Secretary is seeking public comments on these procedures and requirements.

#### *Summary of the Regulation*

#### **Summary of Available Benefits and Secondary Nature of Benefits (§ 102.2, § 102.84)**

The benefits available under this program are medical benefits, benefits for lost employment income, and survivor death benefits.

As explained in § 102.2(b), the SEPPA establishes that the government is a secondary payor for most benefits available under the program. Thus, benefits paid under this program are generally secondary to any obligation of any third-party payor, described in § 102.3(aa), to pay for or provide such benefits. Requesters generally must provide the names of all other third-party payors that have already provided benefits, that are expected to do so in the future, or that may have a duty to do so. These payors include, but are not limited to: insurance companies, workers' compensation programs, the Federal Employees' Compensation Act (FECA) Program, or the Public Safety

Officers' Benefit (PSOB) Program, a program within the United States Department of Justice that provides payments to public safety officers and their survivors, including death payments for officers killed in the line of duty. If such a third-party payor has paid for or provided the type of benefits requested under this program, the Secretary will only pay such benefits in an amount necessary to supplement the payments already provided. For example, if a requester were otherwise entitled to \$10,000 in medical benefits from this program and the requester's health insurance company (a third-party payor) has paid \$5,000 for the covered medical benefits and services, the program would pay the requester \$5,000 (the amount the requester is entitled to under this program, reduced by the amount the requester is entitled to from third-party payors). As explained later in the preamble, upon payment of benefits under the Smallpox Vaccine Injury Compensation Program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payor with a legal or contractual obligation to pay for, or provide, such benefits.

#### **Description of Eligible Requesters (§ 102.10(a))**

(1) *Smallpox vaccine recipients*, as defined in § 102.3(y).

A person who has received a smallpox vaccine is only considered a "smallpox vaccine recipient," for purposes of this program, if he or she meets the criteria described in this regulation. Specifically, he or she must have been in a covered occupation (including health care workers, law enforcement officers, public safety personnel, and supporting personnel), received a smallpox vaccine as a participant in an approved smallpox emergency response plan, and sustained a covered injury, described later in this preamble. The exact requirements for smallpox vaccine recipients are set forth in § 102.3(x). For example, this regulation provides that, in order to be eligible, a smallpox vaccine recipient must have received the smallpox vaccine between January 24, 2003, and January 23, 2004, unless the period is extended by the Secretary. In order to be covered by the program, a smallpox vaccine recipient must also have volunteered for and been selected to be a member of a smallpox emergency response plan before the time that the Secretary publicly announces that an active case of smallpox has been identified anywhere in the world. For this reason, persons who become members of smallpox emergency

response plans in order to respond to a case of smallpox that has already occurred will not be considered "smallpox vaccine recipients." Likewise, persons who receive the smallpox vaccine as members of the military or members of the public who receive the smallpox vaccine voluntarily, and not as part of an approved smallpox emergency response plan, are not entitled to benefits under the program.

(2) *Vaccinia contact*, as defined in § 102.3(bb).

The SEPPA imposes specific restrictions as to which persons who have contracted vaccinia from another person may be eligible for benefits under this program. The specific requirements pertaining to vaccinia contacts are set forth in § 102.3(bb). As explained in that section, vaccinia contacts are only eligible for benefits under this program if they can show that they contracted vaccinia as a result of contact with a person who either meets the definition of a smallpox vaccine recipient (except that the vaccine recipient does not need to sustain a covered injury) or who was accidentally inoculated by such a person. For this reason, if the source of a contact's exposure to vaccinia is a person who received a smallpox vaccine other than under an approved smallpox emergency response plan, the contact would not fall within the regulation's definition of a "vaccinia contact" and would not be eligible for benefits under the program. For example, the contacts of members of the military and State Department personnel who receive the smallpox vaccine for their employment, but not as part of an approved smallpox emergency response plan, would not be entitled to benefits under this program. Likewise, the contacts of members of the general public who receive the smallpox vaccine voluntarily, and not as part of an approved smallpox emergency response plan, would not be covered under this program. In addition, vaccinia contacts must have contracted vaccinia during the effective period of the Declaration (between January 24, 2003, and January 23, 2004, unless extended by the Secretary), or within 30 days after the end of such period, and must have sustained a covered injury.

(3) *Certain survivors of deceased smallpox vaccine recipients or vaccinia contacts*, as defined in § 102.3(z).

Categories of eligible survivors and the priority of such survivors to receive benefits from the program are discussed in the section of this preamble concerning death benefits (the only type of benefit survivors are eligible to receive).

(4) *Representatives of estates of deceased smallpox vaccine recipients or vaccinia contacts.*

Representatives of estates of deceased smallpox vaccine recipients or vaccinia contacts may file Request Packages with the program as long as they are seeking benefits on behalf of the deceased person's estate.

#### Benefits Available to Different Categories of Requesters (§ 102.30)

An eligible requester who is a smallpox vaccine recipient or a vaccinia contact may be entitled to receive either medical benefits or benefits for lost employment income or both as long as they provide the proper documentation. For example, such requesters must submit documentation showing that they have out-of-pocket reasonable and necessary medical expenses as a result of a covered injury or its health complications in order to receive medical benefits, and documentation showing that they lost employment income as a result of a covered injury or its health complications in order to receive benefits for lost employment income. Such documentation requirements are discussed later in this preamble.

An eligible requester who is the survivor of a deceased smallpox vaccine recipient or vaccinia contact may be entitled to receive a death benefit.

The estate of a deceased smallpox vaccine recipient or vaccinia contact may be eligible to receive medical benefits or benefits for lost employment income or both if such benefits were accrued during the deceased person's lifetime as a direct result of a covered injury or its health complications, but were not paid during the deceased person's lifetime. However, the estate would not be eligible to receive payments for benefits that were not accrued during the deceased person's lifetime. For example, the estate would not be entitled to benefits for projected lost employment income that the person might have accrued if he or she had not died.

#### Covered Injuries (§ 102.20—§ 102.21)

Covered injuries are defined in § 102.3(g) and set out in subpart C of this rule. Covered injuries are those injuries in smallpox vaccine recipients or vaccinia contacts that the Secretary determines are more likely than not (*i.e.*, by a preponderance of the evidence) the direct result of the administration of a covered countermeasure (including a smallpox vaccine) or of vaccinia acquired through accidental vaccinia inoculation. Because even survivors of, and representatives of estates of,

deceased smallpox vaccine recipients and vaccinia contacts must demonstrate that the deceased person sustained a covered injury, a requester will not be deemed eligible for benefits under the program unless the Secretary determines that an eligible smallpox vaccine recipient or vaccinia contact sustained a covered injury.

One way that requesters can demonstrate that they sustained a covered injury is by demonstrating that they sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table (the table) within the required time interval, as set out in § 102.21. In accordance with the SEPPA, a smallpox vaccine recipient or vaccinia contact shall be presumed to have sustained a covered injury as the direct result of the administration of, or exposure to, the smallpox vaccine if the requester submits sufficient documentation demonstrating that he or she sustained an injury included on the table, with the onset of the first symptom or manifestation within the time interval specified on the table. The injury must also meet the table's definitions and requirements, set forth in § 102.21(b). In such circumstances, the Secretary will presume, solely for purposes of the program, that the smallpox vaccine recipient or vaccinia contact's injury was caused by the smallpox vaccine or exposure to vaccinia. 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 and that it first manifested itself within the time interval listed.

In directing the Secretary to establish a table with such a presumption, Congress did not direct the Secretary to make this presumption conclusive. In the Secretary's view, it would be inconsistent with the purposes of the SEPPA to make this presumption absolutely conclusive. For this reason, based on his review of the submitted documentation and other relevant evidence, the Secretary may determine that an injury meeting the table requirements was more likely than not (*i.e.*, by a preponderance of the evidence) caused by other factors and was not caused by the smallpox vaccine or exposure to vaccinia (*e.g.*, if the Secretary determined that the medical records demonstrated that an individual's injury of encephalopathy was caused by a car accident that occurred post-vaccination and not by the smallpox vaccine or exposure to vaccinia). In these circumstances, which we expect to occur rarely, the Secretary could rebut the table presumption and

decide that the requester may not be entitled to benefits under the program.

Requesters who believe they sustained an injury included on the table, but did not meet all the table requirements (*e.g.*, the first manifestation of the injury did not become apparent within the required time interval), or requesters who believe they sustained an injury not included on the table, may still be able to demonstrate that the injury is one that is covered under the program. In order to establish a covered injury, such requesters may need to submit sufficient relevant medical documentation (such as isolation of vaccinia from the injured part of the body) or scientific evidence (such as results of studies published in peer-reviewed medical literature). In order to establish a covered injury, the Secretary, upon review of this evidence, must conclude that, more likely than not, the injury was actually caused by the administration of a covered countermeasure or by vaccinia through accidental inoculation during the time periods set forth by law. In other words, 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 provided under the SEPPA, this determination, as with all other actions by the Secretary under this Act, is not reviewable by any court.

Any injury that the Secretary considers minor is not a covered injury. For example, covered injuries do not include expected skin reactions or expected minor scarring at the vaccination or inoculation site. No benefits will be paid for these reactions, as stated in § 102.20(b).

#### Medical Benefits—Summary and Calculation (§ 102.31 and § 102.80)

Medical benefits that may be available under the program are described in § 102.31. They include payment(s) or reimbursement for medical services and medical items that the Secretary determines are reasonable and necessary for the diagnosis or treatment of a covered injury or its direct health complications (*sequelae*). Past, current, and expected future medical services and items may be included in medical benefits.

In making determinations about which medical services and items provided in the past were reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a health care practitioner. In considering benefits for

future medical services and items, the Secretary will consider statements by health care practitioners with expertise in the medical issues involved (for example, a statement by a treating neurologist concerning services and items likely to be needed to address neurological issues) concerning those services and items that appear likely to be needed in the future to diagnose or treat the covered injury or its health complications.

In order for a requester to receive medical benefits for a health complication, the health complication must have resulted from the covered injury and not be more likely due to other factors or conditions. Examples of health complications include complications of a covered injury that occur as part of the natural course of the underlying disease, an adverse reaction to a prescribed medication or diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat the injury.

If a smallpox vaccine recipient or vaccinia contact dies before filing for, or being paid, benefits for the cost of medical services or items accrued during his or her lifetime as a result of a covered injury or its health complications, the deceased person's estate may be paid such medical benefits. Because such payments are for medical expenses accrued as a result of a covered injury while the injured person was alive, the cause of death does not have to be related to the covered injury for these medical benefits to be paid.

The calculation of medical benefits is described in § 102.80. There are no caps on medical benefits. However, the Secretary may limit the payment of such benefits to the amounts he considers reasonable for those services and items he considers reasonable and necessary. In addition, payment of medical benefits or reimbursement of costs for medical services and items by the program is secondary to the obligations of any third-party payor, such as the United States (except for payment of benefits under this program), State or local government entities, private insurance carriers, employers, or any other third-party payors that may have a statutory or contractual obligation to pay for or provide medical benefits.

When the Secretary has determined that the requester is eligible for medical benefits and that all of the documentation is available by which he can compute the amount, he will do the following, consistent with the calculations described in § 102.80:

(1) Determine which medical expenses that have been submitted are

reasonable and necessary to diagnose or treat a covered injury or its health complications.

(2) Compute all those reasonable medical expenses, including medical services and items provided in the past, and anticipated future medical expenses.

(3) Deduct from his computation the total amount paid, or payable, by all other third-party payors. This will be the basis for the program's payment. For example: An eligible, injured individual incurred \$5,000 in reasonable and necessary medical expenses. If the individual's insurance company paid \$3,000, and the individual is responsible for the \$2,000 balance (due to deductibles and co-payments), then the Secretary will pay a medical benefit of \$2,000.

As explained elsewhere in the preamble, the Secretary may make a payment of medical benefits and later pursue such a payment from a third-party payor with an obligation to pay for or provide the medical services or items.

#### Lost Employment Income—Summary and Calculation (§ 102.32 and § 102.81)

Lost employment income benefits that may be available under the program are set out in § 102.32. The program will provide benefits for lost employment income (secondary to other benefits that may be available to the requester) based on the number of days of work that the injured person lost as a result of the covered injury or its health complications (including diagnosis and treatment). These benefits are a percentage of the employment income lost and are based on the number of eligible work days for which such income was lost. Employment income includes the injured person's gross employment income. The lost work days do not have to be consecutive, and partial days of lost work are included in the calculation. For example, if an individual's workday is eight hours and he or she missed four hours a day for doctors' appointments on two different days, the eight hours of work missed will be considered one total day of lost work. As described in § 102.32(c), a day in which an individual used paid leave (e.g., sick leave or vacation leave) in order to be paid for lost work will not be considered a day for which employment income was lost and will not be used in calculating benefits for lost employment income. The only exception to this rule is in a case in which the injured person's employer restores the paid leave taken and puts the requester in the same position as if he or she had not used paid leave on the lost work day (i.e., treats the employee

as if he or she did not take paid leave by taking back the payments made when the leave was used and giving back the leave to the employee for future use).

Under the SEPPA, the program cannot pay for the first five days of lost employment income resulting from a covered injury or its health complications, unless the injured individual lost employment income for 10 or more work days (in which case, all of the lost work days will be included in the calculation). For this reason, if an individual lost a total of four days of employment income as a result of a covered injury, he or she will not be eligible for any benefits for lost employment income.

The calculation of benefits for lost employment income is described in § 102.81. The annual cap on benefits for lost employment income for a requester is \$50,000. A requester may use documents such as pay slips, earning and leave statements, and other documents concerning the injured individual's salary and benefits, to document his or her employment income. The benefit terminates once the requester reaches the age of 65. Benefits that represent future lost employment income will be adjusted to account for inflation. It is important to remember that future lost employment income will be calculated based on an individual's employment income at the time the covered injury was sustained (except for the inflation adjustment provided for in this regulation) and will not be based on an individual's anticipated future employment income. The lifetime cap for this benefit is equal to the amount of the death benefit available under the PSOB Program in the same fiscal year in which the lifetime cap is reached (currently approximately \$262,100, but subject to change). However, this lifetime limitation does not apply if the Secretary determines that an individual has a covered injury considered to be a total and permanent disability under section 216(i) of the Social Security Act. For this reason, a requester deemed to have a permanent and total disability by the Secretary may be eligible to receive up to \$50,000 a year until he or she reaches the age of 65.

As with medical benefits, if a smallpox vaccine recipient or vaccinia contact dies before filing for, or being paid, benefits for lost employment income incurred during his or her lifetime as a result of a covered injury or its health complications, the representative of that person's estate may file for such benefits on behalf of the estate. Because this payment is made for loss of employment income that accrued while the injured person

was alive, the death does not have to be related to the covered injury for these benefits to be paid.

Once the Secretary has determined that he has all the information necessary to compute lost employment income, the calculation will be made as follows, as set out in § 102.81:

(1) If the eligible individual lost five days or fewer of employment income, then there will be no benefits for lost employment income.

(2) If the eligible individual lost six to nine days of employment income, then the Secretary will subtract five days from the number of lost work days; if the eligible individual lost 10 or more days of employment income, then every lost work day will be counted.

(3) The Secretary will multiply the injured individual's daily gross employment income (including income from self-employment) at the time of the covered injury by the number of lost work days (as computed above). This figure will be adjusted to account for inflation, as appropriate.

(4) The Secretary will compute 75% of the lost employment income if the injured individual had one or more dependents (at the time of the covered injury) or 66 2/3% of the lost employment income if there were no dependents (at the time of the covered injury). This calculation will serve as the basis for the lost employment income benefit.

(5) The amount of payment will be reduced by any benefit that the requester is entitled to receive from a third-party payor (e.g., a workers' compensation program). However, the Secretary may make a payment of lost employment income and later pursue such a payment from a third-party payor with an obligation to pay for or provide the benefit (e.g., the Secretary can pay a benefit for lost employment income to a requester with a claim pending in a State workers' compensation program, and then has a right to recover such a payment from the State if its program determines that such a benefit is due the requester).

(6) The payments made will be subject to an annual cap of \$50,000. The benefits paid in lost employment income will be subject to a lifetime cap, as discussed above, unless the Secretary determines that a requester has a covered injury considered to be a total and permanent disability under section 216(i) of the Social Security Act.

No State law workers' compensation lien may be maintained on any benefit for lost employment income paid under this program.

**Death Benefits—Summary and Calculation** (§ 102.11, § 102.33, and § 102.82)

Certain survivors of smallpox vaccine recipients or vaccinia contacts who died as a direct result of a covered injury or its health complications may be eligible for death benefits, as set out in § 102.11 (eligible survivors and their priority to receive death benefits), § 102.33 (general description of death benefits) and § 102.82 (calculation of death benefits).

The SEPPA provides that death benefits under this program may be available under two different calculations. The "standard calculation" is a lump-sum payment to eligible survivors and is described in § 102.82(c). In general, this method is based on the death benefit available under the PSOB Program. The "alternative calculation" is only available to surviving dependents who are younger than the age of 18, as described in § 102.82(d). This method is based upon the deceased person's employment income at the time of the covered injury.

**Eligible Survivors and Priorities for Receiving Death Benefits**

With limited exceptions, the Smallpox Vaccine Injury Compensation Program follows the requirements of the PSOB Program with respect to the categories of eligible survivors (known in the PSOB Program as beneficiaries) and the order of priority for payments of death benefits to them. The order of priority for survivors to receive death benefits under the program is subject to changes made in the future under the PSOB Program concerning eligible survivors and their priority to receive death benefits.

Currently, the categories of eligible survivors under the PSOB Program are as follows: (1) Surviving spouses; (2) surviving eligible children; (3) individuals designated by the deceased person as the beneficiaries under the deceased person's most recently executed life insurance policy; and (4) surviving parents. Such survivors, as defined under the PSOB Program, are also eligible survivors under this program. Currently, a surviving child is considered eligible under the PSOB Program if he or she is an individual who is a natural, illegitimate, adopted, or posthumous child, or stepchild, of the deceased person, and is 18 years of age or younger, or between 19 and 23 years of age and a full-time student, or is over 18 years of age and incapable of self-support because of physical or mental disability.

The SEPPA included two additional categories of survivors under this program who are not eligible survivors under the PSOB Program: (5) Legal guardians of deceased minors without surviving parents; and (6) surviving dependents who are younger than the age of 18 (some of whom may also fall within the category of surviving eligible children). As discussed below, special criteria apply to the final category of eligible survivors.

Under current practices, in the event that the deceased eligible individual is survived by a spouse and eligible children, the spouse will receive 50% of the death benefit and the children will divide the remaining 50% equally. If there are no surviving eligible children, then the spouse receives the entire benefit; if there is no surviving spouse, then the children divide the benefit in equal shares. In the event that the deceased injured individual has no surviving spouse or children, the individual designated by the deceased individual as the beneficiary under his or her most recently executed life insurance policy will receive the death benefit. If there is no life insurance policy or no surviving designated beneficiary under such a policy, the parents will divide the death benefit in equal shares. If none of these categories of survivors exists, the legal guardian of a deceased minor (who was a smallpox vaccine recipient or vaccinia contact) with no living parent will receive the death benefit, if applicable. As explained in § 102.11(b)(5), surviving dependents younger than the age of 18 will have the same priority as surviving eligible children.

Only the legal guardians of persons qualifying both as surviving eligible children under the PSOB Program and as dependents younger than the age of 18 can choose between a proportional death benefit under the standard and the alternative methods of payment. Survivors eligible under the PSOB Program's categories of survivors (e.g., spouses, parents, certain insurance designees, and surviving eligible children) who do not qualify as dependent minors are only covered under the standard calculation. Dependents who are minors and who do not qualify under another category of eligible survivors (for example, eligible surviving children of the deceased) are only covered by the alternative method of payment.

**Death Benefits Under the Standard Calculation, Described in § 102.82(c)**

Under the "standard calculation," the amount of the death benefit that can be paid under the program in a particular

fiscal year will equal the amount of the death benefit available under the PSOB Program in the same fiscal year (without regard to any reduction in PSOB Program death benefits due to a limitation in appropriations). The amount of the PSOB Program death benefit, which is subject to change, is currently approximately \$262,100. Survivors who already collected, or are eligible to collect, death benefits under the PSOB Program are not eligible to receive Smallpox Vaccine Injury Compensation Program death benefits under the standard calculation. Survivors receiving a death benefit under the standard calculation from this program will receive the difference between any disability benefit paid under the PSOB Program and the death benefit available under the standard calculation if the PSOB Program disability benefit was underpaid due to a limitation in appropriations.

Death benefits under the standard calculation will be reduced by the amount of lost employment income benefits that were paid under this program either to the deceased individual during his or her lifetime, or to his or her estate after death. For example, if a smallpox vaccine recipient received \$40,000 from the program during his lifetime in benefits for lost employment income and later died, his survivors would be entitled to receive a total of approximately \$222,100 in this fiscal year (the approximate \$262,100 death benefit, minus the \$40,000 in benefits for lost employment income paid to the injured person during his lifetime).

#### Death Benefits Under the Alternative Calculation, Described in § 102.82(d)

Payments made under the "alternative calculation" of death benefits are based on the deceased person's employment income at the time he or she sustained the covered injury. Under this calculation, 75% of the deceased person's employment income (determined in the same manner as employment income for purposes of lost employment income benefits) at the time he or she sustained the covered injury resulting in death will be paid annually until the youngest of the dependents reaches the age of 18. However, the maximum annual amount that may be paid to dependents (in total) under the alternative calculation is \$50,000. No lifetime caps apply to death benefits under this alternative calculation.

Death benefits under this alternative calculation are available only to surviving dependents who are younger than the age of 18. In order for such

surviving dependents to receive payments under the alternative calculation as opposed to the standard calculation, the legal guardian of all the dependents younger than the age of 18 must choose to receive a proportionate share of the benefits under this calculation on their behalf, as described in § 102.82(d)(1). In the event that multiple dependents have different legal guardians, each legal guardian is responsible for choosing the calculation of death benefits on behalf of the dependents of whom he or she is the legal guardian. For this reason, the legal guardian of several individuals who qualify both as surviving dependents younger than the age of 18 and as surviving eligible children cannot select a death benefit under the standard calculation for some of those dependents and a death benefit under the alternative calculation for other dependents. For those survivors who are eligible for a death benefit under both calculations, the particular circumstances (e.g., the age of the survivors, the employment income of the deceased person at the time of the covered injury) will determine which method of calculation will provide the greatest financial benefit.

If dependent survivors choose to receive death benefits under the alternative calculation, no death benefits will be paid to those dependents under the standard calculation. However, such payments would not preclude other eligible survivors of equal priority from receiving a proportionate death benefit under the standard calculation. For example, if a deceased smallpox recipient or vaccinia contact is survived by two dependents younger than the age of 18 from a prior marriage and by a spouse who is not the legal guardian of the dependents, the legal guardian of the two dependents could choose to receive a 50% share of the death benefit for the dependent children under the alternative calculation and the surviving spouse would still be able to receive his or her 50% share of the death benefit under the standard calculation. As another example, if a deceased smallpox recipient is survived by two minor, dependent children, one whose living parent is the deceased person's surviving spouse and another whose living parent is the deceased person's former spouse, the surviving spouse could receive a 50% share of the death benefit under the standard calculation and each of the dependent children would be eligible for a proportionate share (25%) of the death benefit available under the standard calculation

or the alternative calculation, as determined by the children's respective legal guardians. Although the Program will generally apportion death benefits among multiple eligible survivors, it will not do so on behalf of dependents receiving death benefits under the alternative calculation if the dependents share the same legal guardian (because such payments would be made to the legal guardian on behalf of all of the dependents for whom he or she is the legal guardian). The legal guardian would be expected to apportion the award appropriately.

Death benefits paid to survivors under this alternative calculation are secondary to all payments made, or expected to be made in the future, by any third party payor for: (i) Compensation for the deceased person's loss of employment income on behalf of the dependents receiving death benefits under the alternative calculation, or their legal guardian(s); (ii) disability, retirement, or death benefits in relation to the deceased person on behalf of the dependents receiving death benefits under the alternative calculation, or their legal guardian(s); and (iii) life insurance benefits on behalf of the dependents receiving death benefits under the alternative calculation. Such secondary benefits are described in § 102.83(d)(3)(A). Reductions will not be made if such benefits were paid to other persons (for example, if a retirement benefit was paid to the surviving spouse who is not the dependents' legal guardian, no deduction would be made to the dependents' death benefit to account for the benefit the spouse received). In calculating such reductions, the Secretary will have discretion to apportion over multiple years any lump-sum third-party payments. The Secretary has a right to recover benefits paid under this program from third-party payors that have an obligation to pay for or provide such benefits.

As with other determinations made under this regulation, any determination concerning the calculation and payment of death benefits is not subject to any judicial review.

#### Filing a Request Package (§ 102.40–§ 102.41)

A Smallpox Vaccine Injury Compensation Request Form (hereinafter "Request Form") available from the program and all the eligibility and benefits documentation comprise the Smallpox Vaccine Injury Compensation Request Package (hereinafter "Request Package"). In order for a requester to have his or her request reviewed by the program, the

requester must submit, at a minimum, a completed Request Form postmarked within the filing deadlines established by this regulation. If requesters choose to use a commercial carrier such as Federal Express, United Parcel Service, Emery, etc., or a private delivery service, in the absence of a postmark, the date that the Request Form or Request Package is marked as received by the delivery service will be considered the equivalent of a postmark. Requesters must send their Request Forms and Request Packages to the applicable address listed in § 102.41.

#### Representatives of Requesters (§ 102.44)

This program has been designed so that requesters do not need to retain the services of lawyers to pursue benefits under this program. However, as provided in § 102.44, requesters may have a legal or personal representative submit the Request Form and/or Request Package on their behalf. A legally competent requester must certify on the Request Form that he or she has authorized the representative to submit the Request Package on his or her behalf. Requesters who are minors or legally incompetent adults will require the assistance of a representative (who does not need to be a lawyer). Representatives of requesters who are minors or adults determined by a court to be legally incompetent are required to submit specific documentation, in addition to the documentation generally required of requesters, which is described in § 102.63. The representative of a requester is required to submit the documents that would ordinarily be required of the requester. For example, if this regulation requires a requester to submit his or her medical records, the requester's representative would be required to submit the same records on behalf of the requester.

The Secretary will direct all correspondence to, and communicate exclusively with, a requester's representative unless the Secretary is advised that the representation has stopped. As explained above, although legal representation is permitted, it is not needed for filing for program benefits. As described in § 102.44(d), the Secretary will not be responsible for the payment of any fees for the services of legal or personal representatives or for any associated costs.

#### Filing Deadlines (§ 102.42)

Smallpox vaccine recipients who have a covered injury have one year from the date of a smallpox vaccination administered during the effective period of the Declaration (between January 24, 2003, and January 23, 2004, unless the

Secretary extends the time period) to submit a Request Form. This deadline applies even if the requester's injury was the direct result of a covered countermeasure other than the smallpox vaccine (e.g., cidofovir) that was administered after the vaccine administration. Vaccinia contacts have two years to submit their Request Forms from the date of the onset of the covered injury, as documented in their medical records. Because the SEPPA, in its discussion of filing deadlines, refers to requests based on the administration of the smallpox vaccine and requests based on accidental vaccinia inoculation, the filing deadlines that apply to Request Forms filed by smallpox vaccine recipients or vaccinia contacts are the same filing deadlines that apply to Request Forms filed by the survivors or the representatives of the estates of deceased smallpox vaccine recipients and vaccinia contacts. However, as explained later in the preamble, if a smallpox vaccine recipient or vaccinia contact filed a timely Request Form and later died, his or her survivors (or the representative of his or her estate) could file an amendment to that Request Package outside of the filing deadline. Because the administration of smallpox covered countermeasures other than the smallpox vaccine (cidofovir and its derivatives or Vaccinia Immune Globulin), in the context of this program, generally relates back to complications arising from the administration of the smallpox vaccine or of accidental vaccinia inoculation, the filing deadlines set forth in § 102.42 extend to the administration of such other covered countermeasures.

In the event that the Secretary amends the Table of Injuries, requesters have an extended filing deadline, based on the effective date of the table amendment, which will be published in the **Federal Register**. However, the extended filing deadline only applies if the table amendment enables a person who could not establish a table injury before the amendment to establish such an injury.

To speed the review of eligibility, requesters should file all documentation required for eligibility determinations by the filing deadline. However, a requester will meet the filing deadline requirement by submitting only the completed and signed Request Form by that deadline, with documentation to follow. Request Forms not filed within the governing filing deadline will not be processed, and the requester will not be considered for any program benefits.

#### Amendments to Request Packages (§ 102.46)

The filing of amendments to previously filed Request Packages is discussed in § 102.46. As explained in that section, if a smallpox vaccine recipient or vaccinia contact filed a Request Package, but later dies, his or her survivors or the representative of his or her estate may amend the Request Package. However, a requester filing such an amended request will only be entitled to benefits under the program if the original Request Form (filed by the smallpox vaccine recipient, vaccinia contact, or representative) was filed within the applicable filing deadline. If such an amendment is filed, all of the documentation submitted with the original Request Package will be considered part of the amended Request Package and the survivor or estate representative need not resubmit such documentation. Requesters are responsible for notifying the program of any changes in circumstances that may have an impact on the Secretary's eligibility and benefits determinations.

#### Documentation Needed for the Secretary To Determine Eligibility (§ 102.50–§ 102.54)

Requesters or their representatives must submit appropriate documentation to allow the Secretary to determine if the requesters are eligible for program benefits. The documentation required will vary somewhat depending on whether the requester is filing as a smallpox vaccine recipient, vaccinia contact, survivor, or representative of an estate.

#### Medical Records Required of All Requesters To Establish a Covered Injury (§ 102.50)

Because all Request Packages filed with the program, including those filed by survivors or representatives of the estates of deceased persons, must relate back to a smallpox vaccine recipient or vaccinia contact who sustained a covered injury, all requesters must submit medical records sufficient to demonstrate to the Secretary that a covered injury was sustained by a smallpox vaccine recipient or a vaccinia contact. Section 102.50(a) describes the medical records that are generally required in order for a requester to establish that a covered injury was sustained. The Secretary will use the records submitted, as well as any other available evidence, to evaluate either whether an injury set out in the table and meeting the table's requirements was sustained or whether an injury was sustained as the direct result of

receiving a covered countermeasure (including a smallpox vaccine) or of contracting vaccinia through accidental exposure. The program will consider copies of medical records to be the same as the original records.

Although the medical records described in § 102.50(a) are those that will generally be required for all requesters, requesters may also submit additional documentation, as provided for under § 102.50(b). As described in § 102.50(d), the Secretary may determine that particular records described in § 102.50(a) are not necessary for particular requesters (for example, if certain medical records provide the exact same information as other records that are submitted) or that additional records may be required in order to make a covered injury determination (for example, in cases in which a preexisting condition may be the cause of the current injury).

If certain medical records are unavailable to a requester, the requester must submit a statement describing the reasons for the records' unavailability and the reasonable efforts the requester has made to obtain them. The Secretary may, at his discretion, accept such a statement from the requester instead of the required medical records, if the circumstances so warrant, as set forth in § 102.50(c).

If a smallpox vaccine recipient or vaccinia contact died and his or her survivors seek a death benefit under the program, the Secretary will need to review the medical records to determine whether the death was the direct result of a covered injury. As explained in § 102.53(d), the medical records reviewed for this purpose may be the same as those submitted for the covered injury determination.

In making covered injury determinations, the Secretary may consider all of the scientific evidence available (e.g., published articles concerning a relationship between the smallpox vaccine and an injury) and consult with qualified medical experts.

#### Documentation a Smallpox Vaccine Recipient Must Submit To Be Deemed Eligible (§ 102.51)

As described above, a smallpox vaccine recipient must submit medical records that are sufficient to show that he or she sustained a covered injury, including medical records produced after the vaccination from all hospitals, clinics, or providers. In order to show eligibility, such a requester must also submit a completed and signed Request Form and the documentation described in § 102.51. As noted in § 102.51(b), a requester may submit a certification

form, available from the program, completed by the entity (e.g., State government, private employer) that participated in the administration of the smallpox vaccine or other covered countermeasure to the smallpox vaccine recipient as part of a smallpox emergency response plan in place of documentation otherwise required concerning the requester's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan.

#### Documentation a Vaccinia Contact Must Submit To Be Deemed Eligible (§ 102.52)

A requester who is a vaccinia contact must submit a completed and signed Request Form and the documentation described in § 102.52. Among the required documentation is documentation identifying the individual who was the source of the accidental vaccinia inoculation. However, if such documentation is unavailable, for example, if the source of the exposure to vaccinia is unknown, the Secretary has the discretion to accept other documentation providing evidence of the source of such exposure. For example, the Secretary may accept an affidavit signed by the requester explaining the circumstances under which he or she contracted the vaccinia. If this information is supportive of the vaccinia contact contracting vaccinia from a smallpox vaccine recipient (as defined in this regulation, except that the recipient need not sustain a covered injury) or from the contact of such a person, the Secretary may accept such an affidavit in place of the required documentation.

#### Documentation a Survivor Must Submit To Be Deemed Eligible (§ 102.53)

A requester who is a survivor of a deceased smallpox vaccine recipient or vaccinia contact must submit a completed and signed Request Form, the documentation discussed above that the deceased person would have had to submit if he or she were alive at the time of filing, and the documentation required of survivor requesters. These requirements are described in § 102.53.

#### Documentation a Representative of a Deceased Person's Estate Must Submit for the Estate To Be Deemed Eligible (§ 102.54)

A requester who is the representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact, seeking benefits under the program on behalf of the estate, must submit a completed and signed Request Form, the documentation discussed above that

the deceased person would have had to submit if he or she were alive at the time of filing, and the documentation required of requesters who are estate representatives. These requirements are described in § 102.54.

#### Documentation Needed for the Secretary To Calculate Benefits (§ 102.60–§ 102.63)

In addition to the documentation requesters must submit for the Secretary to make eligibility determinations (including the determination that a covered injury was sustained), requesters must submit documentation to enable the program to calculate the type and amount of benefits available. Because the benefits available under the program are generally secondary to benefits received from third-party payors, it may be possible that certain requesters who are deemed eligible will not receive benefits from the program. Sections 102.60–102.63 describe the documentation that is required for requesters seeking particular types of benefits.

Although the program will accept such documentation at any time after a Request Form is filed, a requester need not submit any of the documentation pertaining to benefits until the Secretary has informed the requester that he or she is eligible under the program. The submission of benefits documentation is described in § 102.43(b) and is designed to ease the documentary burden on requesters who do not know whether or not they will be deemed eligible. Requesters need not submit benefits documentation until they have been notified by the Secretary that they are eligible.

In order to calculate the amount of each type of benefit available, the program requires requesters to provide documentation of every third-party payor that may have paid for or provided the benefits requested, or that may have an obligation to do so. The information required concerning such third-party payors with respect to each type of benefit available under the program is described in § 102.60–§ 102.62.

Requesters seeking medical benefits must also submit documentation concerning the amount paid or expected to be paid by such third-party payors for the medical services or items for which payment is being sought under the program. Third-party payors of medical benefits include, but are not limited to, medical insurance, Medicaid, Medicare, and any other source of medical recompense. An example of the documentation necessary to satisfy this requirement is an Explanation of

Benefits form issued by the requester's health insurance company.

Third-party payors of benefits for lost employment income include, but are not limited to, the requester's employer, disability insurance, and workers' compensation programs. In order to satisfy his or her obligations under § 102.61, a requester may need to submit documentation including his or her earnings and leave statements, information concerning the number of hours in the requester's standard work day, as well as documentation concerning any lost work benefits programs or payments.

Requesters seeking death benefits will have to submit different documentation concerning third-party payors depending on whether they are seeking death benefits under the standard calculation described in § 102.82(c) or are choosing a death benefit under the alternative calculation described in § 102.82(d). For example, survivors seeking a death benefit under the standard calculation must submit documentation concerning PSOB Program death and disability benefits. The legal guardian of survivors seeking a death benefit under the alternative calculation must submit documentation concerning a broader group of existing or potential third-party payors (described fully in the death benefits calculation section of this preamble and set forth in § 102.83(d)(3)(A)). Requesters seeking death benefits must submit other documentation described in § 102.62.

Before payments will be made, the representatives of requesters who are minors or legally incompetent adults must submit additional documentation described in § 102.63. Because some of this documentation may be time-consuming to obtain (e.g., obtaining a court decree establishing a guardianship of the estate for a legally incompetent adult), the requester can wait until a benefits calculation has been made, and a written approval has been issued, before submitting such documentation.

#### Determinations the Secretary Will Make (§ 102.70–§ 102.74)

When the Secretary receives a completed and signed Request Form or Request Package postmarked in the appropriate time frame, he will conduct two separate reviews, as described in § 102.70. First, he will determine whether the requester is eligible. Second, the Secretary will determine the type and amount of benefits that may be paid (if any).

If the Request Package does not include sufficient documentation to determine eligibility, the Secretary will

send written notice to the requester (or his or her representative) identifying the documentation that is needed, as provided for in § 102.71. The requester will be given 60 days to submit the required documentation. If, after reasonable efforts to obtain the documents, the documentation remains unavailable, the requester must submit a letter explaining the circumstances to the Secretary. The Secretary also has the discretion to accept a letter meeting the requirements set out in § 102.71 as a substitute for the unavailable documentation. Once the Secretary has sufficient documentation to make an eligibility determination, he will make that decision in a timely manner.

If the Secretary determines that a requester is not eligible for benefits under the program, he will inform the requester (or his or her representative) of the disapproval in writing. As described in § 102.72(a), the Secretary will provide information as to the options available to the requester, including the requester's right to seek reconsideration of the eligibility decision.

If the Secretary determines that a requester meets the eligibility requirements, he will notify the requester in writing of this decision, at which point the Secretary will review the Request Package in order to calculate the type and amount of the benefits. If the Request Package does not have sufficient documentation for the Secretary to calculate the amount of the benefits, the Secretary will notify the requester in writing of the documentation he requires to complete the calculation. As with the eligibility documentation, the requester will be given 60 days to submit the required documentation or provide a letter setting forth the circumstances that make the records unavailable. Again, the Secretary may accept a letter meeting the requirements set forth in § 102.71 as a substitute for the unavailable documentation. Once the Secretary has sufficient documentation to calculate a requester's benefits, the Secretary will complete this calculation in a timely manner.

As set out in § 102.73, once the Secretary has calculated the amount of the benefits and determined that payment is to be made, he will inform the requester of the approval in writing and then initiate payment. Under § 102.74, if the Secretary disapproves a request, which the Secretary may do at any time, he will so notify the requester (or his or her representative) in writing and provide information as to the options available to the requester, including the requester's right to seek

reconsideration of the Secretary's decision.

#### Payment of All Benefits Under the Program (§ 102.83)

The Secretary's options in paying all benefits under the program are described in § 102.83. If the Secretary determines that there is a reasonable likelihood that payments of medical benefits, benefits for lost employment income, or death benefits paid under the alternative calculation (described in § 102.82(d)) will be required for a period in excess of a year from the date the Secretary determines that the requester is eligible for such benefits, the Secretary may pay such benefits through a lump-sum payment, annuity or medical insurance policy, or appropriate structured settlement agreement, as long as the payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total amount of such benefits that the requester is eligible to receive.

As described in § 102.83(b), lump sum payments will generally be made through electronic funds transfers to requesters' accounts. If a requester is a minor, the payment will be transferred to the account of the minor's legal guardian (generally, the minor's parent). The legal guardians of minor requesters under this program will be required to use the payments for the benefit of the minor. Such legal guardians are subject to applicable State law requirements concerning payments made on behalf of minors (e.g., become the guardian of the minor's estate or establish an account with State court supervision, if required by State law). In administering this program, consistent with the practice of the PSOB Program in paying death benefits on behalf of minors, the Secretary will not require proof that the legal guardian has taken such actions. Section 102.83(b) describes the requirements pertaining to lump sum payments made on behalf of adults considered legally incompetent.

As provided in § 102.83(c), the Secretary may choose to make interim payments of benefits under the program (in other words, issue a payment for a certain type or portion of program benefit prior to making the final benefits payment) in order to get certain benefits to a requester more quickly than would otherwise be possible. For example, the Secretary may pay medical benefits for past services or items to an eligible requester whose covered injury has resulted in substantial medical bills before making the final determination concerning the payment of future medical benefits. In certain cases, the

Secretary may make an interim payment of benefits even before a final eligibility or benefits determination is made. The Secretary expects such instances to be rare, and the requester in such circumstances must agree to repay the Secretary for any benefits later determined to be improper.

#### The Tax Consequences of Receiving Benefits From the Program

The Secretary has asked the Internal Revenue Service (IRS) to provide prompt guidance on the tax consequences of receiving benefits under SEPPA. The IRS intends to publish guidance before the end of the year that will give requesters who receive benefits under the program the information they would need to meet any Federal tax responsibilities. The IRS has committed to working with the Secretary to ensure that requesters have ready access to the tax information and assistance with any additional questions they may have.

#### The Secretary's Right To Recover Benefits Paid Under the Program From Third-Party Payors (§ 102.84)

As described elsewhere in this preamble, the payment of benefits under this program is generally secondary to benefits available from other third-party payors. The category of third-party payors that have primary responsibility to pay for or provide such benefits is different for each type of benefit available under this program. Such third-party payors are discussed in the sections of the preamble concerning the different types of benefits. As described in § 102.84, after the Secretary pays benefits under this program, he will be subrogated to the rights of the requester, meaning that the Secretary may assert a claim against any third-party payor with a legal or contractual obligation to pay for, or provide, such benefits. The Secretary may recover from such a third-party payor the amount of benefits the third-party payor has or had an obligation to pay for or provide. For example, if the Secretary pays a requester \$10,000 in benefits for lost employment income under this program and a State workers' compensation program later determines that it is obliged to pay the requester \$5,000 in workers' compensation benefits, the Secretary may pursue a claim against the State for the \$5,000 (because the Secretary, as the secondary payor, would only be obligated to pay the requester \$5,000 in benefits for lost employment income). Any benefits paid under this program are not subject to any lien by any primary third-party payor.

#### The Reconsideration Process (§ 102.90)

Every individual who has filed a Request Package and has received a determination by the Secretary either denying eligibility for benefits or denying a category or amount of benefits requested, has a right to seek reconsideration of the Secretary's determination(s). Although such initial determinations are characterized as Secretarial determinations, this decision-making authority will be delegated to the Smallpox Vaccine Injury Compensation Program Office. The requester or his or her representative must send a letter seeking reconsideration to the Associate Administrator, Special Programs Bureau, Health Resources and Services Administration, at the address provided in § 102.90(b). The letter must be received by the Department within 60 calendar days of the date of the Department's determination letter. The letter should state the reasons why the Secretary should reconsider his decision. No new documentation can be included with this letter.

The Associate Administrator, Special Programs Bureau, will convene a panel to review all cases seeking reconsideration. The panel will consist of qualified individuals who are independent of the Smallpox Vaccine Injury Compensation Program Office. The panel will review the Request Package that was before the Secretary at the time of the determination (and will not consider any new documentation submitted by the requester).

After reviewing the case, the panel will make a recommendation to the Associate Administrator, Special Programs Bureau, who will then make a final determination as to whether or not the requester is eligible for benefits or as to the type and/or amount of benefits that may be paid. The Associate Administrator will inform the requester or his or her representative in writing of the determination(s) and of the reasons. This decision will be considered the Secretary's final action on the issue for which reconsideration was sought. Requesters may not seek review of such a decision.

If the Associate Administrator's final decision is that a requester who was determined to be ineligible for benefits is, in fact, eligible, then the Secretary will make a determination as to the type and amount of benefits to be paid. The requester then has a right to seek reconsideration of the Secretary's determination on that issue.

#### Secretary's Review Authority and No Further Review of Determinations Made Under This Regulation (§ 102.91, § 102.92)

As described in § 102.91, the SEPPA authorizes the Secretary to review at any time, and at his own motion or on application, any determination made concerning eligibility, entitlement to benefits, and the calculation and payment of benefits under the Program and authorizes the Secretary to affirm, vacate, or modify such determination in any manner the Secretary deems appropriate.

As explained in § 102.92, once the Secretary has made a final decision as to eligibility or type or amount of benefits and the requester has exercised his or her right to reconsideration, section 262(f)(2) of the Public Health Service Act does not allow any further review of that decision by any court or administrative body (unless the President specifically directs further administrative review). Given this broad statutory prohibition against further review, no determination made under this part (including, but not limited to, eligibility determinations, benefits calculations, payment decisions, and reconsideration decisions) will be subject to any review by Federal or State courts.

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

Through the enactment by the SEPPA of part C, Title II of the Public Health Service Act (PHS Act), the Secretary was authorized to establish and administer the Smallpox Vaccine Injury Compensation Program. Congress authorized the Secretary to issue regulations implementing the SEPPA as the Secretary deems reasonable and necessary, and provided that the initial implementing regulations could be published by interim final rule. In accordance with that statutory authority, the Secretary is herein establishing the procedures and requirements to govern the program.

In addition, the Secretary has determined, under 5 U.S.C. 553(b), that it is contrary to the public interest to follow proposed rulemaking procedures (*i.e.*, issuing a proposed rule, with an accompanying solicitation of public comments) 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 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 sooner this regulation is in effect, the sooner the program is implemented and the sooner potential requesters will be able to assess their eligibility to receive benefits from the program. Once this implementing regulation is in effect, the Secretary expects individuals who believe that they may be entitled to benefits under the program will file requests for such benefits within a short time frame. In addition, publishing this regulation promptly is necessary given that the governing filing deadlines, as applied to particular requesters, will begin to occur within a short period of time.

For the same reasons, the Secretary has determined that there is good cause to waive a delay in the rule's effective date. Nonetheless, as noted above, comments on the procedures and requirements set forth in this interim final rule will be accepted at the above listed address for a period of 60 days following the publication of the rule in the **Federal Register**. Thus, although the rule is effective immediately upon publication, the Secretary will consider the comments received and, based on them, may amend the procedures and/or requirements pertaining to this program.

#### Economic and Regulatory Impact

*Regulatory Flexibility Act and Executive Order 12866.* 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 rule will not have a significant impact on a substantial number of small entities. Specifically, both the benefits and the burdens associated with this interim final rule will go almost entirely to individuals who are filing as requesters with the program. Any burdens on small entities associated with the implementation of this final rule (e.g., completing a certification form concerning a smallpox vaccine recipient who was vaccinated under the auspices of a small entity as part of a smallpox emergency response plan, providing records to requesters seeking to comply with the regulation's documentation requirements) will be minimal in nature. Moreover, the number of small entities affected in this way will be very small in number.

The Secretary has also determined that this proposed 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 proposed rule is not a "major rule" within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801.

Nonetheless, the Secretary believes that a discussion of the factors that led to the creation of the smallpox vaccination plan and of the Smallpox Vaccine Injury Compensation Program, as well as the likely impact of both programs, is warranted. As described earlier in this preamble, 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% or variola minor with death rates approaching 1%. Those who survived were frequently left with significant disabilities, such as blindness. Smallpox vaccine was an essential tool for the successful global eradication of smallpox, announced by the World Health Organization in 1980. Despite such eradication, concern exists that terrorists may have access to 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 emergency 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, and as described earlier, the Secretary issued a Declaration Regarding Administration of Smallpox Countermeasures on January 24, 2003. In this Declaration, the Secretary stated 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 emergency response plans identified by State or local government entities or the Department of Health and Human Services, certain public safety personnel, and certain personnel associated with specific Federal facilities abroad. The Secretary recommended that such persons receive the smallpox vaccine to ensure that essential 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.

As already stated, the SEPPA was enacted on April 30, 2003. This statute authorized the Secretary to establish the Smallpox Vaccine Injury Compensation Program (the program). This program has been appropriated \$42 million for the administration of the program and the payment of benefits under the program. The purpose of the program is to provide benefits to eligible members of smallpox emergency response plans who sustain a covered injury as the result of receiving the smallpox vaccine (or other smallpox covered countermeasures). In addition, certain persons who come in contact with a vaccinated member of a smallpox

emergency response plan (or the contact of such a person) and sustain a covered injury may be eligible for benefits. As noted above, death benefits are also available to survivors of individuals whose death resulted directly from a covered injury.

The availability of benefits to injured persons (and certain survivors, in the case of death) under this program was considered an important step in the implementation of the Administration's smallpox vaccination plan and in the nation's preparedness to face potential terrorist events involving the smallpox virus. Prior to the enactment of the SEPPA, and the establishment of this program, eligible smallpox vaccine recipients and vaccinia contacts were only entitled to benefits for medical care or for lost employment income related to covered injuries that were otherwise available from other third-party payors (e.g., State workers' compensation programs). In addition, pursuant to the Homeland Security Act of 2002, certain smallpox vaccine recipients and vaccinia contacts could pursue legal actions relating to covered injuries under the Federal Torts Claims Act (FTCA). The latter option was limited insofar as awards under the FTCA are available only to the extent that negligence can be shown in relation to the vaccine production or administration. The SEPPA expanded the benefits available to eligible smallpox vaccine recipients and vaccinia contacts through the establishment of a no-fault administrative compensation program that supplements the benefits available from other third-party payors.

The Administration has worked to remove other disincentives to smallpox vaccination through approved smallpox emergency response plans (e.g., providing appropriate guidelines for pre-vaccination screening for potential contraindications, engaging in post-vaccination surveillance and data collection).

Because it is impossible to quantify the risk of potential terrorist incidents involving the smallpox virus, it is impossible to assess the contribution that a group of first responders vaccinated with the smallpox vaccine through smallpox emergency response plans will provide to the population of the United States. In making benefits available to eligible individuals, the Administration is removing a disincentive that may be a barrier against first responders and others receiving the smallpox vaccination as participants in approved smallpox emergency response plans. In removing this disincentive, the program is likely

to increase the nation's preparedness in the face of uncertainty. In addition, the establishment of the program ensures that individuals who sustain covered injuries as the direct result of such vaccinations (or of other smallpox covered countermeasures) or of accidental vaccinia inoculation will be afforded appropriate benefits, including payment for related medical services and items.

As of September 2003, approximately 38,400 vaccinations have been administered to civilians under approved smallpox emergency response plans. Of those, approximately 800 have reported medical injuries to the CDC through the Vaccine Adverse Events Reporting System (VAERS). Such reports have included three fatalities and 92 serious injuries. Some of those who have reported injuries may not be eligible for the Smallpox Vaccine Injury Compensation Program, either because the injury is not covered by the Act (e.g., because the injury is excluded as a minor injury or because the injury is neither listed on the table nor is there evidence linking the smallpox vaccine to the occurrence of the injury) or because the individual is not eligible under the SEPPA (e.g., the requester received the smallpox vaccine, but not as a participant in an approved smallpox emergency response plan). Nevertheless, these recorded injuries indicate a possible injury rate of about 2% of the vaccinated population.

The \$42 million appropriated to the Program, in addition to covering administrative costs, was projected by Congress to cover the provision of benefits to eligible requesters. This figure was reached after consideration of the projected number of covered injuries and related deaths, projected medical costs related to the covered injuries, and the projected number of lost work days resulting from such covered injuries. The fact that program benefits are generally only available if such benefits are not available from other third-party payors (e.g., medical benefits will not be paid for medical services or items if a requester's health insurance company has an obligation to pay for or provide such services or items), or are generally only available in an amount necessary to supplement benefits available from third-party payors, was also considered.

It should be noted that the smallpox vaccination program that was being considered by Congress and the Administration when the \$42 million appropriation was made contemplated that up to 2–3 million individuals could be vaccinated through approved smallpox emergency response plans if individuals representing all of the

occupations described in the SEPPA (including health care workers, firefighters, and public safety personnel) fully participated in the smallpox vaccination program. The number of individuals who have received the smallpox vaccine under approved smallpox emergency response plans to date is substantially smaller than the number of such vaccinees that were considered possible if the smallpox vaccination program reached full participation. As of September 2003, approximately 38,400 vaccinations were administered under approved smallpox emergency response plans. For this reason, the number of individuals eligible to receive benefits under the program may in fact be a small percentage of the numbers originally considered. Given that the number of individuals who have volunteered to receive the smallpox vaccine under approved smallpox emergency response plans is significantly smaller than the total number of potential vaccinees likely considered in devising the \$42 million appropriation, the program expects the adverse events associated with the smallpox vaccination program and the amount of benefits paid by the program (which will depend, on large part, upon the amount of medical services and items, as well as lost employment income, relating to covered injuries) to be similarly smaller than what was considered in calculating the \$42 million appropriation. Of course, this expectation may change over time depending upon many factors, including the number of volunteers who receive the smallpox vaccine under approved smallpox emergency response plans in the future, as well as new scientific findings concerning the existence of causal relationships between particular medical conditions and the smallpox vaccine (as well as other covered countermeasures and vaccinia contracted through accidental exposure).

In establishing the procedures described in this regulation, the Secretary has made operational decisions that will assist eligible requesters to receive benefits in a prompt and fair manner. For example, requesters are not required to obtain the services of an attorney in order to obtain benefits under the program, but are permitted to appoint a representative to assist them in filing a Request Package if this will be helpful to the requester.

In addition, the Secretary has made an effort to be flexible in circumstances in which a requester is unable to submit documentation that would otherwise be required in order to establish eligibility and entitlement to benefits. For

example, if a requester has made a good faith effort to obtain medical records, but is unable to access such records (e.g., if a physician's practice is no longer in business), the Secretary may choose to accept a statement by the requester describing the reasons for the records' unavailability and the reasonable efforts the requester has made to obtain them in place of the unavailable medical records. Likewise, if a vaccinia contact is unable to identify the source of his or her exposure to vaccinia, this interim final rule enables the requester to submit an affidavit explaining the circumstances under which he or she contracted the vaccinia. If this information is consistent with the vaccinia contact contracting vaccinia from an eligible vaccinee or the contact of such a person (e.g., the vaccinia contact works in a hospital and was in close contact with several individuals who received the smallpox vaccine under an approved smallpox emergency response plan and, to the best of his or her knowledge, was not in close contact with any person who received the smallpox vaccine outside such a plan), the Secretary may accept such an affidavit in place of the required documentation.

*Unfunded Mandates Reform Act of 1995.* The Secretary has determined that this interim final rule 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.

*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 interim final 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 interim final rule may have a positive impact on the disposable income and poverty elements of family well-being to the extent that families of injured persons (and of other persons deemed eligible to receive benefits under this part) receive, or are helped by, benefits paid under this part without imposing a corresponding burden on them.

*Impact of the New Rule.* In this interim final rule, the Secretary establishes the procedures and requirements applicable to requesters filing for benefits available under the program. This interim final rule is based on the SEPPA. It will have the effect of enabling certain eligible individuals who sustained covered injuries as the direct result of receiving a covered countermeasure under the Secretary's Declaration, or as a direct result of vaccinia contracted through accidental vaccinia inoculation in the case of certain vaccinia contacts, to receive benefits under the program. In the event that an otherwise eligible smallpox vaccine recipient or vaccinia contact has died, his or her estate and/or survivors may be entitled to certain benefits. This interim final rule sets out the eligibility requirements that apply to the program, and the documentation that must be submitted.

*Paperwork Reduction Act of 1995.* In accordance with section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA) of 1995, the Department is required to solicit public comments, and receive final Office of Management and Budget (OMB) approval, on any information collection requirements set forth in rulemaking. As indicated, in order to implement the SEPPA, certain information is required as set forth in §§ 102.50–102.63 of this rule.

In accordance with the PRA, we have submitted and obtained OMB approval on this data collection and reporting of this information. An emergency review

was needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure the timely availability of data as necessary to ensure the provision of benefits to eligible petitioners. Delaying the data collection would delay implementation of the statutory purpose of providing benefits to eligible individuals who sustained covered injuries, particularly because the statutory filing deadlines for certain eligible requesters may occur as early as January 2004. Implementing this regulation and providing benefits as soon as possible will ensure that the intent of SEPPA in making these benefits to eligible individuals will be implemented, to the extent possible. OMB has approved this collection, with a 180-day approval period. During this period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on the requirements set forth.

*Collection of Information:* The Smallpox Vaccine Injury Compensation Program.

*Description of Respondents:* Individuals who are members of smallpox emergency response plans who received a smallpox vaccine and sustained a covered injury from it or from other covered countermeasures. Individuals who were injured by vaccinia from contact with a vaccinated member of a smallpox emergency response plan or other vaccinia contacts also qualify. In addition, some survivors of smallpox vaccine recipients or of vaccinia contacts may be eligible for death benefits and the estates of such deceased persons may receive certain benefits.

*Estimated Annual Reporting:* The estimated annual reporting for this data collection is a total of six hours for reviewing and completing the Smallpox Vaccine Injury Compensation Request Form as well as the time to obtain and provide medical and financial documentation for eligibility and the computation of benefits. The estimated annual response burden is as follows:

Form	Number of respondents	Responses per respondent	Hourly response	Total burden hours	Wage rate	Total hour cost
Request Form and Supporting Documentation .....	1,250	1	5	6,250	\$37.50	\$234,375
Certification .....	1,250	1	1	1,250	37.50	46,875
<b>Total .....</b>	<b>2,500</b>	<b>.....</b>	<b>.....</b>	<b>7,500</b>	<b>.....</b>	<b>281,250</b>

According to CDC's Vaccine Adverse Event Reporting System (VAERS), there are reports of three fatalities and 92 serious injuries (out of approximately 800 total reported injuries) based on the administration of approximately 38,400 smallpox vaccinations to volunteers within the civilian sector (as of September 2003). The program recognizes the difficulty inherent in predicting the number of individuals who will file for benefits under approved smallpox emergency response plans. Nonetheless, with the anticipation of additional individuals receiving the smallpox vaccine, plus a number of potential contact cases, the program predicts that there may be up to 1,250 requesters. It is important to note that a large number of such requesters filing Request Forms with the program may not be eligible for payments under the program for a variety of reasons (*e.g.*, they sustained minor injuries that do not qualify as covered injuries, the Secretary determines that their injuries do not qualify as table injuries and that there is insufficient evidence to establish causation, they received the smallpox vaccine outside of an approved smallpox emergency response plan, or they did not file their Request Form within the governing filing deadlines).

The annual burden estimate includes the time required to review and complete the Request Form as well as the time to obtain and provide further documentation necessary for eligibility and benefits determinations. Comments on this information collection activity should be sent to Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053; FAX: (202) 395-6974.

#### List of Subjects in 42 CFR Part 102

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

Dated: October 27, 2003.

**Elizabeth M. Duke,**

*Administrator, Health Resources and Services Administration.*

Approved: December 8, 2003.

**Tommy G. Thompson,**

*Secretary.*

■ For the reasons stated above, the Department of Health and Human Services amends part 102 of 42 CFR as follows:

■ 1. The authority section for part 102 is revised to read as follows:

**Authority:** 42 U.S.C. 216, 42 U.S.C. 239-239h.

■ 2. In part 102, add sections 102.1—102.20 to read as follows:

### PART 102—SMALLPOX VACCINE INJURY COMPENSATION PROGRAM

#### Subpart A—General Provisions

Sec.

- 102.1 Purpose.
- 102.2 Summary of available benefits.
- 102.3 Definitions.

#### Subpart B—Persons Eligible to Receive Benefits

- 102.10 Eligible requesters.
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#### Subpart C—Covered Injuries

- 102.20 How to establish a covered injury.
- 102.21 Smallpox (Vaccinia) Vaccine Injury Table.

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- 102.30 Benefits available to different categories of requesters under this program.
- 102.31 Medical benefits.
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#### Subpart E—Procedures for Filing Request Packages

- 102.40 How to obtain forms and instructions.
- 102.41 How to file a request package.
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#### Subpart F—Required Documentation To Be Deemed Eligible

- 102.50 Medical records necessary to establish that a covered injury was sustained.
- 102.51 Documentation a smallpox vaccine recipient must submit to be deemed eligible by the Secretary.
- 102.52 Documentation a vaccinia contact must submit to be deemed eligible by the Secretary.
- 102.53 Documentation a survivor must submit to be deemed eligible by the Secretary.
- 102.54 Documentation a representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact must submit to be deemed eligible by the Secretary.

#### Subpart G—Required Documentation for Eligible Requesters to Receive Benefits

- 102.60 Documentation an eligible requester seeking medical benefits must submit.
- 102.61 Documentation an eligible requester seeking benefits for lost employment income must submit.
- 102.62 Documentation an eligible requester seeking a death benefit must submit.
- 102.63 Documentation a representative filing on behalf of an eligible requester who is a minor or a legally incompetent adult must submit.

#### Subpart H—Secretarial Determinations

- 102.70 Determinations the Secretary must make before benefits can be paid.
- 102.71 Insufficient documentation for eligibility and benefits determinations.
- 102.72 Sufficient documentation for eligibility and benefits determinations.
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#### Subpart I—Calculation and Payment of Benefits

- 102.80 Calculation of medical benefits.
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#### Subpart J—Reconsideration of the Secretary's Determinations.

- 102.90 Reconsideration of the Secretary's eligibility and/or benefits determinations.
- 102.91 Secretary's review authority.
- 102.92 No additional judicial or administrative review of determinations.

#### Subpart A—General Provisions

##### § 102.1 Purpose.

This part implements Section 2 of the Smallpox Emergency Personnel Protection Act of 2003 (the Act). The Act directs the Secretary of Health and Human Services to establish procedures for providing benefits to certain individuals who sustained a covered injury as the direct result of the administration of the smallpox vaccine or other covered countermeasure, and to certain individuals who sustained a covered injury as the direct result of accidental vaccinia inoculation through contact with certain persons vaccinated with the smallpox vaccine or with individuals accidentally inoculated by them. Also, if the Secretary determines that an individual died as a result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

##### § 102.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to requesters deemed eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury or its health complications, as described in § 102.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 102.32.

(3) Death payments to survivors if the Secretary determines that the death of the smallpox vaccine recipient or vaccinia contact was the direct result of

a covered injury, as described in § 102.33.

(b) The benefits paid under the Program, with the exception of death benefits paid under § 102.82(c), are secondary to any obligation of any third-party payor to pay for such benefits. Death benefits paid under § 102.82(c) are secondary to death and disability benefits under the PSOB Program. The benefits paid under the Program usually will only be paid after the requester has pursued all other available coverage from all third-party payors with an obligation to pay for or provide such benefits (e.g., medical insurance for medical items, workers' compensation program(s) for lost employment income). However, as provided in § 102.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payor makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payor with a legal or contractual obligation to pay for, or provide, such benefits.

### § 102.3 Definitions.

This section defines certain words and phrases found throughout this part. Words and phrases that are used only in limited situations are defined in specific sections of this part.

(a) *Accidental vaccinia inoculation* means the transfer of vaccinia virus from an existing vaccination site (the skin surface where the vaccinia virus entered the body through vaccination) or inoculation site (the skin or mucous membrane surface where the vaccinia virus entered the body through means other than vaccination) on a person to a second person, resulting in a contact case.

(b) *Act* means the Smallpox Emergency Personnel Protection Act of 2003, Pub. L. 108–20, 117 Stat. 638.

(c) *Approval* means a decision by the Secretary that the requester will be paid benefits under the Program.

(d) *Benefits* means benefits and/or compensation.

(e) *Contact case* means a case in which a person developed an initial vaccinal lesion or vaccinal infection through an exposure other than being vaccinated him/herself.

(f) *Covered countermeasure* means smallpox (vaccinia) vaccines, cidofovir and its derivatives, or Vaccinia Immune Globulin, when used to prevent or treat the smallpox disease or control or treat the adverse effects of vaccinia vaccination or inoculation or of the administration of another countermeasure.

(g) *Covered injury* means an injury determined by the Secretary, in accordance with subpart C of this part, to be:

(1) An injury meeting the requirements of the Table, which is presumed to be the direct result of the administration of a smallpox vaccine or accidental vaccinia inoculation; or

(2) More likely than not, the direct result of:

(A) The administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration, in the case of a smallpox vaccine recipient; or

(B) Vaccinia contracted through accidental vaccinia inoculation (and not the result of receiving a smallpox vaccine) during the effective period of the Declaration (or within 30 days after the end of such period), in the case of a vaccinia contact.

(h) *Declaration* means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the **Federal Register** on January 28, 2003 (68 FR 4212).

(i) *Dependent* means a person who would be considered a dependent by the Internal Revenue Service.

(j) *Disapproval* means a decision by the Secretary that the requester will not be paid benefits under the Program.

(k) *Effective period of the Declaration* means the time span specified in the Declaration (January 24, 2003 until and including January 23, 2004), unless extended by the Secretary.

(l) *FECA Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under the Federal Employees' Compensation Act (5 U.S.C. 8101 *et seq.*), as amended, and implemented by the United States Department of Labor in regulations codified at 20 CFR Part 10, as amended.

(m) *Health care practitioner* means a health care provider licensed by a State and authorized to diagnose and prescribe medications and other treatments or authorized to provide primary or specialty care.

(n) *Injury* means an injury (including death), disability, illness, or condition.

(o) *Legally incompetent* means a person who is considered to lack legal capacity under applicable State law.

(p) *Program* means the Smallpox Vaccine Injury Compensation Program.

(q) *Public Safety Officers' Benefits Program (PSOB Program)* means the Program established under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, and implemented by the United States

Department of Justice in regulations codified at 28 CFR Part 32, as amended.

(r) *Requester* means a smallpox vaccine recipient, vaccinia contact, survivor, or representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact (on behalf of the estate) who files a Request Package, or on whose behalf a Request Package is filed, under this part.

(s) *Request Form* means the form designated by the Secretary as the request form for purposes of this part.

(t) *Request Package* means the Request Form, all documentation submitted by or on behalf of the requester, and all documentation obtained by the Secretary as authorized by or on behalf of the requester for determinations of eligibility and benefits under this part.

(u) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

(v) *Smallpox emergency response plan* means a State, local, or Department of Health and Human Services plan, approved by the Secretary, detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

(w) *Smallpox (Vaccinia) Vaccine Injury Table or Table of Injuries* means the table of injuries included at § 102.21, including the definitions and requirements set forth at § 102.21(b).

(x) *Smallpox vaccine recipient* means a person:

(1) Who has been a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties who has volunteered and been selected to be a member of a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified within or outside of the United States;

(2) Who is or will be functioning in a role identified in a smallpox emergency response plan;

(3) To whom a smallpox vaccine is administered pursuant to a smallpox emergency response plan during the effective period of the Declaration; and

(4) Who sustained a covered injury.

(y) *State* means any State of the United States of America, the District of Columbia, United States territories,

commonwealths, and possessions, the Republic of the Marshall Islands, the Republic of Palau, and the Federated States of Micronesia.

(z) *Survivor* means a survivor of a deceased smallpox vaccine recipient or vaccinia contact meeting the requirements of § 102.11.

(aa) *Third-party payor* means the United States (other than for payments of benefits under this Program) or any other third-party, including any State or local governmental entity, private insurance carrier, or employer, with a legal or contractual obligation to pay for or provide benefits.

(bb) *Vaccinia contact* means an individual who:

(1) Contracted vaccinia during the effective period of the Declaration (or within 30 days after the end of such period);

(2) Prior to contracting vaccinia, was accidentally inoculated by a person:

(A) Meeting the criteria set forth in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury); or

(B) Who was accidentally inoculated by a person meeting the criteria set forth in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury); and

(3) Sustained a covered injury.

### Subpart B—Persons Eligible To Receive Benefits

#### § 102.10 Eligible requesters.

(a) The following requesters may, as determined by the Secretary, be eligible to receive benefits from this Program:

(1) Smallpox vaccine recipients, as described in § 102.3(x);

(2) Vaccinia contacts, as described in § 102.3(bb); or

(3) Survivors, as described in § 102.3(z) and § 102.11.

(4) Representatives of the estates of deceased smallpox vaccine recipients or vaccinia contacts (*i.e.*, individuals authorized to act on behalf of the deceased person's estate under applicable state law, such as an executor).

(b) If a smallpox vaccine recipient or vaccinia contact dies, his or her survivor(s) or the representative of his or her estate may file a new Request Package (or Request Package(s)) or amend a previously filed Request Package. A new Request Package may be filed whether or not a Request Package was previously submitted by or on behalf of the deceased person, but must

be filed within the filing deadlines described in § 102.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in § 102.46.

(c) The benefits available to different categories of requesters are described in § 102.30.

#### § 102.11 Survivors.

(a) *Survivors of individuals who died as the direct result of a covered injury.* If the Secretary determines that a smallpox vaccine recipient or vaccinia contact died as the direct result of a covered injury (or injuries), his or her survivor(s) may be eligible for death benefits.

(b) *Survivors who may be eligible to receive benefits and order of priority for benefits.*

(1) The Act uses the same categories of survivors and order of priority for benefits as established and defined by the PSOB Program, except as provided in paragraphs (b)(3), (b)(4), and (b)(5) of this section.

(2) The PSOB Program's categories of survivors (known in the PSOB Program as beneficiaries) and order of priority for receipt of death benefits are detailed under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 *et seq.*), as amended, as implemented in 28 CFR Part 32, as amended.

(3) In the PSOB Program, the person who is survived must satisfy the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased smallpox vaccine recipient or vaccinia contact who would otherwise have been eligible under this part.

(4) Unlike the PSOB Program, if there are no survivors eligible to receive death benefits under the PSOB Program (as set forth in paragraph (b)(2) of this section), the legal guardian of a deceased minor who was a smallpox vaccine recipient or vaccinia contact may be eligible as a survivor under this Program. Such legal guardianship must be determined by a court of competent jurisdiction under applicable State law.

(5) A surviving dependent younger than the age of 18 whose legal guardian opts to receive a death benefit under the alternative calculation on the dependent's behalf will have the same priority as surviving eligible children under the PSOB Program (consistent with paragraph (b)(2) of this section) even if the dependent is not the surviving eligible child of the deceased person for purposes of the PSOB Program. However, such a dependent may only be eligible to receive benefits

under the alternative death benefits calculation, described in § 102.82(d), and is not eligible to receive death benefits under the standard calculation described in § 102.82(c). Because death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such dependents, the Secretary will not divide or apportion such benefits among the dependents.

(6) Any change in the order of priority of survivors or of the eligible category of survivors under the PSOB Program shall apply to requesters seeking death benefits under this Program on the effective date of the change, even prior to any corresponding amendment to this part. Such changes will apply to Request Packages pending with the Program on the effective date of the change, as well as to requests filed after that date.

### Subpart C—Covered Injuries

#### § 102.20 How to establish a covered injury.

(a) *General.* In order to receive benefits under the Program, a requester must submit documentation showing that a covered injury, as described in § 102.3(g), was sustained. A requester can establish that a covered injury was sustained by demonstrating to the Secretary that a Table injury occurred, as described in paragraph (c) of this section. In the alternative, a requester can establish that an injury was actually caused by a covered countermeasure or accidental vaccinia inoculation, as described in paragraph (d) of this section. The Secretary will consider all relevant medical and scientific evidence, such as medical records and documentation submitted by the requester, when determining whether a covered injury was established. In addition, the Secretary may obtain the views of qualified medical experts in making determinations concerning covered injuries. As set forth in the definition of covered countermeasures, if a covered injury is related to the administration of a covered countermeasure, the countermeasure must have been administered to prevent or treat the smallpox disease or to control or treat the adverse effects of vaccinia vaccination or inoculation or of the administration of another countermeasure. The time periods described in this part for receiving a covered countermeasure (during the effective period of the Declaration) or for vaccinia contracted from accidental vaccinia inoculation (during the effective period of the Declaration or within 30 days after the end of such

period) in relation to a covered injury must also be met.

(b) *Minor injuries.* Any injuries that the Secretary deems minor will not be considered covered injuries. Minor injuries include expected and routine responses to the smallpox vaccine, other covered countermeasures, or accidental vaccinia inoculation that are not severe (e.g., minor scarring or minor local reactions, for instance a mild systemic illness with a generalized maculopapular rash that resolves quickly).

(c) *Table injuries.* A requester may establish that a covered injury occurred by demonstrating that a smallpox vaccine recipient or vaccinia contact sustained an injury listed on the Smallpox (Vaccinia) Vaccine Injury Table, set forth in § 120.21, within the time interval listed on the Table and as defined by the Table's Definitions and Requirements, set forth in § 120.21(b). In such circumstances, the requester need not demonstrate the cause of the injury because the Secretary will presume, only for purposes of making determinations under this subpart, that the injury was the direct result of the administration of a smallpox vaccine or exposure to vaccinia. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based upon his review of the evidence, that a source other than the smallpox vaccine or exposure to vaccinia more likely than not caused the injury. In such circumstances, the Table presumption will be rebutted.

(d) *Injuries for which causation must be proven.* If an injury is not included on the Table or if a requester is unable to meet all of the Table requirements with respect to an injury included on the Table (e.g., onset of the injury within the time interval included on the Table), a requester may establish a covered injury by proving causation. To establish that a covered countermeasure or accidental vaccinia inoculation caused an injury, the requester must demonstrate, by a preponderance of the evidence (more likely than not), that:

(1) In the case of a smallpox vaccine recipient, he or she sustained an injury as the direct result of the administration of a covered countermeasure (including the smallpox vaccine) during the effective period of the Declaration; or

(2) In the case of a vaccinia contact, he or she sustained an injury as the direct result of vaccinia contracted through accidental vaccinia inoculation from a person described in § 102.3(bb)(2) (a person meeting the definition of a smallpox vaccine recipient, except that the person need

not sustain a covered injury, or the contact of such a person), and not as the result of receiving a smallpox vaccine. Such vaccinia must have been contracted during the effective period of the Declaration (or within 30 days after the end of such period). The Secretary will consider an injury that resulted from the administration of a covered countermeasure (other than the smallpox vaccine) to be the direct result of vaccinia contracted through accidental vaccinia inoculation if the covered countermeasure was administered as a result of such vaccinia.

**§§ 102.22–102.29 [Reserved]**

3. In part 102, reserve §§ 102.22–102.29.

**§§ 102.30–102.91 [Added]**

4. In part 102, add sections 102.30–102.91 to read as follows:

**Subpart D—Available Benefits**

**§ 102.30 Benefits available to different categories of requesters under this Program.**

(a) *Benefits available to smallpox vaccine recipients and vaccinia contacts.*

A requester who is an eligible smallpox vaccine recipient or vaccinia contact may be entitled to receive either medical benefits or benefits for lost employment income, or both.

(b) *Benefits available to survivors.* A requester who is an eligible survivor of a smallpox vaccine recipient or vaccinia contact may be entitled to receive a death benefit.

(c) *Benefits available to estates of deceased smallpox vaccine recipients or vaccinia contacts.* The estate of an otherwise eligible deceased smallpox vaccine recipient or vaccinia contact may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased person's lifetime as a result of a covered injury or its health complications, but were not paid while the deceased person was living. Such medical benefits and benefits for lost employment income may be available regardless of whether the death was the direct result of a covered injury or an unrelated factor. The estate of a deceased smallpox vaccine recipient or vaccinia contact may not receive a death benefit.

**§ 102.31 Medical benefits.**

(a) Smallpox vaccine recipients and vaccinia contacts may receive payments or reimbursements for medical services and items that the Secretary determines to be reasonable and necessary to

diagnose or treat a covered injury or a health complication of a covered injury (i.e., sequela). The Secretary may pay for such medical services and items in an effort to cure, counteract, or minimize the effects of any covered injury, or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly benefits to a requester (e.g., a surgical procedure that lessens the amount of time and expense for the treatment of a covered injury). The Secretary may make such payments or reimbursements if the medical services and items have already been provided or if they are likely to be provided in the future. In making determinations about which medical services and items are reasonable and necessary, the Secretary may consider whether those medical services and items were prescribed or recommended by a health care practitioner.

(b) To receive medical benefits for the health complications of a covered injury, a requester must demonstrate that the complications are the direct result of the covered injury. Examples of health complications include, but are not limited to, complications of a covered injury that occur as part of the natural course of the underlying disease, an adverse reaction to a prescribed medication or diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat a covered injury.

(c) The calculation of medical benefits available under this Program is described in § 102.80. Although there are no caps on medical benefits available under this Program, the Secretary may limit payments to the amount he deems reasonable for those services and items he considers reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payor to pay for or provide such services or items to the requester. As provided in § 102.84, the Secretary retains the right to recover medical benefits paid to requesters by third-party payors.

(d) The Secretary may make payments or reimbursements of medical benefits to the estate of a deceased smallpox vaccine recipient or vaccinia contact as long as such benefits were accrued during the deceased person's lifetime as the result of a covered injury or its health complications and were not paid during the deceased person's lifetime.

**§ 102.32 Benefits for lost employment income.**

(a) Requesters who are smallpox vaccine recipients or vaccinia contacts

may be able to receive benefits for loss of employment income incurred as a result of a covered injury (or its health complications, as described in § 102.31(b)). These benefits are a percentage of the employment income lost due to the covered injury or its health complications.

(b) The method and amount of benefits for lost employment income are described in § 102.81. Benefits for lost employment income will be adjusted if there are fewer than 10 days of lost employment income. Benefits provided for lost employment income may also be adjusted for annual and lifetime caps. Payment of benefits for lost employment income is secondary to any obligation of any third-party payor to pay for lost employment income or to provide disability or retirement benefits to the requester. As provided in § 102.84, the Secretary retains the right to recover benefits for lost employment income paid to requesters from third-party payors.

(c) The Secretary is not requiring an individual to use paid leave (e.g., sick leave or vacation leave) to be paid for lost work days. However, if an individual uses such paid leave in order to be paid for lost work days, the Secretary will not consider the days in which such leave was used to be days of lost employment income, unless the individual's employer restores the leave that was used. By restoring paid leave, an employer puts the individual in the same position as if he or she had not used paid leave on the lost work day (i.e., takes back the payments made when the leave was taken and gives back the leave to the employee for future use).

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased smallpox vaccine recipient or vaccinia contact as long as such benefits were accrued during the deceased person's lifetime as the result of a covered injury or its health complications and were not paid to the deceased person during his or her lifetime.

#### § 102.33 Death benefits.

(a) Eligible survivors may be able to receive a death benefit under this Program if the Secretary determines that an otherwise eligible deceased smallpox vaccine recipient or vaccinia contact sustained a covered injury and died as a direct result of the injury. Annual and lifetime caps may apply to the death benefits provided. The method and amount of death benefits are described in § 102.82. As provided in § 102.84, the Secretary retains the right to recover death benefits paid to requesters from

third-party payors. Death benefits may be paid under two different calculations.

(b) The standard calculation, described in § 102.82(c), is based upon the death benefit available under the PSOB Program and is available to all eligible survivors (except for surviving dependents younger than the age of 18 who are not also surviving eligible children). In the event that death benefits were paid under the PSOB Program with respect to the deceased person, no death benefits may be paid under the standard calculation. In addition, death benefits under this standard calculation are secondary to disability benefits under the PSOB Program. Any death benefit paid under the standard calculation will be reduced by the total amount of benefits for lost employment income paid to the smallpox vaccine recipient or vaccinia contact during his or her lifetime and to his or her estate after death.

(c) The alternative calculation, described in § 102.82(c), is calculated based on the person's employment income at the time of the covered injury. This calculation is only available to surviving dependents who are younger than the age of 18. The legal guardian(s) of such surviving dependents must select the death benefit as calculated under this alternative calculation before it will be paid. The payment of a death benefit as calculated under this alternative calculation is secondary to other benefits received (compensation for loss of employment income, death benefits (including PSOB Program death benefits), disability benefits, or retirement benefits on behalf of the dependent(s) or his or her legal guardian or life insurance benefits on behalf of the dependent(s)).

#### Subpart E—Procedures for Filing Request Packages

##### § 102.40 How to obtain forms and instructions.

Interested parties may obtain copies of all necessary forms and instructions by sending a letter through the U.S. Postal Service, commercial carrier, or private courier service, by telephone, or by downloading them from the Program's website.

(a) If using the U.S. Postal Service, interested parties should send letters asking for forms and instructions to the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, Health Resources and Services Administration, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857.

(b) If using a commercial carrier or private courier service, interested parties should send letters asking for forms and instructions to the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814.

(c) For forms and instructions, interested parties can call (888) 496-0338. This is a toll-free number.

(d) Interested parties can download forms and instructions from the Internet at <http://www.hrsa.gov/smallpoxinjury>. Click on the link to "Forms and Instructions."

##### § 102.41 How to file a Request Package.

A Request Package comprises all the forms and documentation that are submitted to enable the Secretary to determine eligibility and calculate payments. Request Packages may be filed through the U.S. Postal Service, commercial carrier, or private courier service. The Smallpox Vaccine Injury Compensation Program Office will not accept Request Packages electronically or by hand-delivery.

(a) If using the U.S. Postal Service, requesters (or their representatives) should send all forms and documentation to the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, Health Resources and Services Administration, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, MD 20857.

(b) If using a commercial carrier or private courier service, requesters (or their representatives) should send all forms and documentation to the Smallpox Vaccine Injury Compensation Program Office, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814.

##### § 102.42 Deadlines for Filing Request Forms.

(a) *General.* Filing deadlines vary depending on whether the injured individual is a smallpox vaccine recipient or a vaccinia contact. In all cases, the filing date is the date the Request Form is postmarked. A legibly dated receipt from a commercial carrier, a private courier service, or the U.S. Postal Service (e.g., the date that a commercial carrier places on the package at the time of drop-off) will be considered equivalent to a postmark. A Request Form will not be considered filed unless it has been completed (to the fullest extent possible) and signed by the requester or his or her representative. After filing a Request

Form within the governing filing deadline, a requester can and should update the Request Form to reflect new information.

(b) *Request forms not filed within deadline.* If the Secretary determines that a Request Form was not filed within the governing filing deadline set out in this section, the Request Form will not be processed and the requester will not be entitled to any benefits under this Program.

(c) *Smallpox vaccine recipients.* All Request Forms filed by, or on behalf of, a smallpox vaccine recipient must be filed within one year of the date of the administration of a smallpox vaccine to the smallpox vaccine recipient. This deadline also applies to a deceased smallpox vaccine recipient's survivor(s) and the representative of his or her estate. This deadline applies to Request Forms concerning injuries resulting from the administration of a smallpox vaccine or other covered countermeasures.

(d) *Vaccinia contacts.* All Request Forms filed by, or on behalf of, a vaccinia contact must be filed within two years after the date of the first symptom or manifestation of onset of the covered injury in the vaccinia contact. This deadline also applies to a deceased vaccinia contact's survivor(s) and the representative of his or her estate. This deadline applies to Request Forms concerning injuries resulting from vaccinia contracted through accidental vaccinia inoculation or from the administration of covered countermeasures (other than the smallpox vaccine) as a result of such accidental vaccinia inoculation.

(e) *Request forms (or amendments to request forms) based on modifications to the table of injuries.* The Secretary may amend the Table set forth in § 102.21. The effect of such an amendment may enable a requester who previously could not establish a Table injury to establish a Table injury. In such circumstances, the requester must file a new Request Form or an amendment to a previously filed Request Form as follows:

(1) If the injured person is a smallpox vaccine recipient, within one year after the effective date of the amendment to the Table; or

(2) If the injured person is a vaccinia contact, within two years after the effective date of the amendment to the Table.

#### § 102.43 Deadlines for submitting documentation.

(a) *Documentation for eligibility determinations.* All eligibility documentation required by the Program

should be filed together with the Request Form. However, if this is not possible, a requester will satisfy the filing deadline as long as the signed Request Form is completed (to the fullest extent possible) and submitted within the governing filing deadline described in § 102.42. The Secretary will not generally begin his review of a requester's eligibility until the documentation necessary for the Secretary to make this determination has been submitted. All such documentation must be submitted before the Program terminates.

(b) *Documentation for benefits determinations.* Although the Secretary will accept documentation required to make benefits determinations (*i.e.*, calculate benefits available, if any) at the time the Request Form is filed or any time thereafter, requesters need not submit such documentation until they have been notified that the Secretary has determined eligibility. The Secretary will not generally begin his review of the benefits available to a requester until the documentation necessary for the Secretary to make a benefits determination has been submitted. All such documentation must be submitted before the Program terminates.

#### § 102.44 Representatives of requesters.

(a) Persons other than a requester (*e.g.*, a lawyer, guardian, friend) may file a Request Package on a requester's behalf as his or her representative. A requester need not use the services of a lawyer to secure benefits under this Program. A representative (who does not need to be a lawyer) is only required, as described in this section, for requesters who are minors or legally incompetent adults. In the event that a representative files on behalf of a requester, the representative will be bound by the obligations and documentation requirements that apply to the requester (*e.g.*, if a requester is required to submit employment records, the representative must file the requester's employment records). The representative must also satisfy the requirements specific to representatives set forth in this regulation. If a requester has a representative, all communications from the Secretary will be directed exclusively to the representative.

(b) *Representatives of legally competent adults.* A requester who is a legally competent adult *may* use a representative to submit a Request Package on his or her behalf. In such circumstances, the requester must certify on the Request Form that he or she is authorizing the representative to

pursue benefits under this Program on his or her behalf.

(c) *Representatives of minors and legally incompetent adults.* A requester who is a minor or a legally incompetent adult *must* use a representative to pursue benefits under this Program on his or her behalf. In such circumstances, the representative must certify, in the place provided on the Request Form, that the requester is a minor or a legally incompetent adult and that the representative is filing on behalf of the requester. In addition, before the requester will be paid by the Program, the representative must submit the documentation described in § 102.63.

(d) *No payment for attorneys' fees or costs.* Because it is not necessary to hire a lawyer to obtain benefits under this Program and because attorneys' fees or other fees and costs to representatives are not covered under the Act, the Secretary will not reimburse such fees or costs.

#### § 102.45 Multiple survivors.

Multiple survivors of the same smallpox vaccine recipient or vaccinia contact may file Request Forms separately or together. Multiple survivors may also submit one set of any required documentation on behalf of all of the requesting survivors as long as such documentation is identical for each survivor.

#### § 102.46 Amending a request package.

(a) *Generally.* All requesters may amend their documentation concerning eligibility until the Secretary has made an eligibility determination. Requesters also may amend their information or documentation concerning the calculation of benefits until the Secretary has made a benefits determination. The Secretary may, at his discretion, accept eligibility or benefits documents even after eligibility or benefits determinations have been made (*e.g.*, the Secretary may accept new documents concerning eligibility after determining that a requester is ineligible and may use such documents to reevaluate the earlier eligibility determination). However, such new documentation will not be used in any reconsideration regarding the initial determination. The Secretary will not consider any documentation submitted after the Program terminates.

(b) *Requesters who are survivors.* If a smallpox vaccine recipient or vaccinia contact submitted a Request Form within the filing deadline, but subsequently dies, his or her survivor(s) may amend his or her Request Package at any time before the Program terminates in order to be considered

eligible for death benefits. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased person's Request Package. However, a survivor filing an amendment to a previously filed Request Package may only be entitled to benefits if the previously filed Request Package was filed within the governing filing deadline. All documentation that has already been submitted with respect to the deceased person will be considered part of the survivor requester's Request Package, and he or she is not required to resubmit such documentation. Survivor requesters must also file an amendment to a Request Package if there is a change in the order of priority of survivors, as described in § 102.11. Such an amendment may be filed at any time before the Program terminates.

(c) *Requests in which benefits are sought by the estate of a deceased smallpox vaccine recipient or vaccinia contact.* If a smallpox vaccine recipient or vaccinia contact submitted a Request Form within the filing deadline, but subsequently dies, a representative of his or her estate may amend his or her Request Package at any time before the Program terminates in order to be considered eligible for benefits. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased person's Request Package. However, a representative of an estate filing an amendment to a previously filed Request Package may only be entitled to benefits if the previously filed Request Package was filed within the governing filing deadline. All required documentation that has already been submitted with respect to the deceased person will be considered part of the amended Request Package, and the representative of the estate is not required to resubmit such documentation.

#### **Subpart F—Required Documentation To Be Deemed Eligible**

##### **§ 102.50 Medical records necessary to establish that a covered injury was sustained.**

(a) In order to establish that a smallpox vaccine recipient or vaccinia contact sustained a covered injury, a requester must submit the following medical records:

(1) All physician, clinic, or hospital outpatient medical records documenting medical visits, consultations, and test results that occurred on or after the date

of the smallpox vaccination or exposure to vaccinia; and

(2) All inpatient hospital medical records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all progress notes, and all test results that occurred on or after the date of the smallpox vaccination or exposure to vaccinia.

(b) A requester may submit additional medical documentation that he or she believes will support the Request Package. Although generally not required if a Table injury was sustained, a requester may need to introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure (including the smallpox vaccine) or vaccinia contracted through accidental vaccinia inoculation.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the requester after he or she has made reasonable efforts to obtain the records, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has taken to obtain the records. The Secretary has the discretion to accept such a statement in place of the unavailable medical records. In this circumstance, the Secretary may require an authorization from the requester (or his or her representative) to try to obtain the records on his or her behalf.

(d) In certain circumstances, the Secretary may require additional medical records to make a determination that a covered injury was sustained (*e.g.*, medical records prior to the date of vaccination or accidental vaccinia exposure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination (*e.g.*, records that are duplicative of other records submitted). If the Program requests additional medical records (or information) from a requester's health care practitioner, then the requester may use a release form in order to have the medical records sent directly to the Program.

##### **§ 102.51 Documentation a smallpox vaccine recipient must submit to be deemed eligible by the Secretary.**

(a) A smallpox vaccine recipient must submit the following documentation in order to be deemed eligible by the Secretary:

(1) A completed (to the fullest extent possible) and signed Request Form.

(2) Documentation demonstrating that the requester:

(A) Is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties who has volunteered and been selected to be a member of a smallpox emergency response plan prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified within or outside of the United States and that the requester is or will be functioning in a role identified in a smallpox emergency response plan; and

(B) Was administered a smallpox vaccine pursuant to an approved smallpox emergency response plan during the effective period of the Declaration.

(3) If the requester's injury relates to the administration of cidofovir or its derivatives or Vaccinia Immune Globulin, and not the smallpox vaccine, documentation demonstrating that the requester was administered such a covered countermeasure during the effective period of the Declaration.

(4) Medical records sufficient to demonstrate that the requester sustained a covered injury, as described in § 102.3(g), in accordance with the requirements set forth in § 102.50.

(b) As an alternative to the documentation described in paragraphs (a)(2)(A)–(B) of this section (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan), a requester may submit a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures through a smallpox emergency response plan, that the requester is a person described in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury). A certification form that may be used for this purpose is available from the Program.

##### **§ 102.52 Documentation a vaccinia contact must submit to be deemed eligible by the Secretary.**

A requester who is a vaccinia contact must submit the following documentation in order to be deemed eligible by the Secretary:

(a) A completed (to the fullest extent possible) and signed Request Form;

(b) Documentation identifying the individual who was the source of the accidental vaccinia inoculation. This

documentation must demonstrate that the source of the vaccinia was an individual described in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury) or an individual who was accidentally inoculated by an individual described in § 102.3(x)(1)–(3) (a person meeting the definition of a smallpox vaccine recipient, except for the requirement that the person sustained a covered injury). If the requester is unable to provide the identity of the person who was the source of the accidental exposure, he or she must explain in writing both why this criterion cannot be met and the circumstances of the accidental vaccinia inoculation that support an individual described above as the source of the accidental vaccinia inoculation. The Secretary has the discretion to accept the requester's statement as evidence of the requester's source of exposure; and

(c) Medical records sufficient to demonstrate that the requester contracted vaccinia during the effective period of the Declaration (or within 30 days thereafter) and sustained a covered injury, as described in § 102.3(g), in accordance with the requirements set forth in § 102.50. These records must be consistent with the requester contracting vaccinia after the accidental vaccinia inoculation described in paragraph (b) of this section.

**§ 102.53 Documentation a survivor must submit to be deemed eligible by the Secretary.**

A requester who is a survivor must submit the following documentation in order to be deemed eligible by the Secretary:

- (a) A completed (to the fullest extent possible) and signed Request Form;
- (b) All of the documentation required in:
- (1) Section 102.51(a)(2)–(4) (documentation requirements for smallpox vaccine recipients), in the case of a deceased smallpox vaccine recipient. The survivor requester may submit a certification, as described in § 102.51(b) in the place of the documentation described in § 102.51(a)(2) (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan); or
  - (2) Section 102.52(b)–(d) (documentation requirements for vaccinia contacts), in the case of a deceased vaccinia contact;
  - (c) A death certificate for the deceased smallpox vaccine recipient or vaccinia

contact. If a death certificate is unavailable, the requester must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the smallpox recipient or vaccinia contact is deceased;

(d) Medical records sufficient to demonstrate that the deceased smallpox vaccine recipient or vaccinia contact died as the result of the covered injury. Such medical records may be the same as those required under § 102.50. If an autopsy was performed on the deceased smallpox vaccine recipient or vaccinia contact, the requester must submit a complete copy of the final autopsy report.

(e) Documentation showing that the requester is an eligible survivor, pursuant to § 102.11 (e.g., birth certificate or marriage certificate); and

(f) A certification, on the place provided on the Request Form, either that there are no other eligible survivors (e.g., for surviving eligible children, a certification that there is no surviving spouse, no other surviving eligible children, and no other surviving dependents younger than the age of 18 who may be eligible for the death benefit under the alternative calculation) or that other eligible survivors exist (along with the information known about such survivors). Section 102.11 lists eligible survivors and the priorities of survivorship.

**§ 102.54 Documentation the representative of the estate of a deceased smallpox vaccine recipient or vaccine contact must submit to be deemed eligible by the Secretary.**

A requester who is the representative of the estate of a deceased smallpox vaccine recipient or vaccinia contact must submit the following documentation in order for the estate to be deemed eligible by the Secretary:

- (a) A completed (to the fullest extent possible) and signed Request Form;
- (b) All of the documentation required in:
- (1) Section 102.51(a)(2)–(4) (documentation requirements for smallpox vaccine recipients), in the case of a deceased smallpox vaccine recipient. The requester may submit a certification, as described in § 102.51(b) in the place of the documentation described in § 102.51(a)(2) (documentation concerning a vaccine recipient's participation in, and receipt of the smallpox vaccine under, an approved smallpox emergency response plan); or
  - (2) Section 102.52(b)–(d) (documentation requirements for

vaccinia contacts), in the case of a deceased vaccinia contact;

(c) A death certificate for the deceased smallpox vaccine recipient or vaccinia contact. If a death certificate is unavailable, the requester must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the smallpox recipient or vaccinia contact is deceased; and

(d) Documentation showing that the requester is the representative of the estate of the deceased smallpox vaccine recipient or vaccinia contact.

**Subpart G—Required Documentation for Eligible Requesters to Receive Benefits**

**§ 102.60 Documentation an eligible requester seeking medical benefits must submit.**

A requester deemed eligible by the Secretary who seeks payment or reimbursement for medical services or items must submit the following, in addition to the documentation submitted under subpart F:

(a) *List of third-party payors.* The requester must submit a list of all third-party payors that may have an obligation to pay for or provide any medical services or items for which payment or reimbursement is being sought under this Program. Such third-party payors may include, but are not limited to, health maintenance organizations, health insurance companies, Medicare, Medicaid, and other entities obligated to provide medical services or items or recompense individuals for medical expenses. Such a list must include the individual's account numbers and other applicable information. If the requester knows of no such third-party payor, he or she must certify to that fact. If the requester becomes aware that a third-party payor may have such an obligation, the requester must inform the Secretary within 10 business days of becoming aware of this information.

(b) *Documents for medical services or items provided in the past.* A requester seeking payment or reimbursement for medical services or items provided in the past must submit an itemized statement from each health care entity (e.g., clinic, hospital, doctor, or pharmacy) and third-party payor listing the services or items provided to diagnose or treat the covered injury or its health complications and the amounts paid or expected to be paid by third parties for such services or items (e.g., an Explanation of Benefits from the individual's health insurance

company). If no third-party payor has an obligation to pay for or provide such services or items, the requester must certify to that fact and submit an itemized list of the services or items provided (including the total cost of such services or items). To assist the Secretary in making a determination as to whether such services or items were reasonable and necessary to diagnose or treat a covered injury or its health complications, the requester may submit, in addition to the required medical records, documentation showing that a health care practitioner prescribed or recommended such services or items. The medical records must support the requested services and items;

(c) *Documents for medical services and items expected to be provided in the future.* A requester seeking payments for medical services or items expected to be provided in the future must submit a statement from one or more health care practitioner(s) (e.g., a treating neurologist for neurologic issues and a treating cardiologist for cardiologic issues) describing those services and items that appear likely to be needed to diagnose or treat the covered injury or its health complications in the future. The medical records must support the requested services and items. A requester must submit documentation, if available, concerning the likely cost of, and the amount expected to be paid by third-party payors for, such services or items.

**§ 102.61 Documentation an eligible requester seeking benefits for lost employment income must submit.**

A requester deemed eligible by the Secretary who seeks benefits for lost employment income from the Program must submit, in addition to the documentation submitted under subpart F, documentation describing:

(a) The number of days (including partial days) of work missed by the smallpox vaccine recipient or vaccinia contact as a result of the covered injury or its health complications for which employment income was lost (e.g., time sheet from pay period reflecting work days missed). As stated in § 102.32(c), days for which an individual used paid leave in order to be paid for lost work will be considered days of work for which employment income was received (unless the individual's employer restores the leave that was used by putting the individual in the same position as if he or she had not used paid leave);

(b) The smallpox vaccine recipient or vaccinia contact's gross employment

income at the time the covered injury was sustained (e.g., the individual's most recent Federal tax return or a pay stub from the time of the covered injury);

(c) Whether the smallpox vaccine recipient or vaccinia contact had one or more dependents at the time the covered injury was sustained (e.g., the individual's most recent Federal tax return); and

(d) All third-party payors that have paid for or that may be required to pay the requester benefits for loss of employment income or provide disability and retirement benefits for which payment or reimbursement is being sought under this Program (e.g., State workers' compensation programs, disability insurance programs, etc.). A requester must submit documentation, if available, concerning the amount of such payments or benefits expected to be paid by third-party payors. If the requester knows of no such third-party payor, he or she must certify to that fact. If, at any time, the requester becomes aware that a third-party payor may have such an obligation, the requester must inform the Secretary within 10 business days of becoming aware of this information.

**§ 102.62 Documentation an eligible requester seeking a death benefit must submit.**

(a) A requester deemed an eligible survivor by the Secretary who seeks a death benefit under § 102.82(c) must submit, in addition to the documentation submitted under subpart F, a certification informing the Secretary whether a disability or death benefit was paid under the PSOB Program with respect to the deceased smallpox vaccine recipient or vaccinia contact. If such a benefit(s) was provided, the requester must submit documentation showing the amount of the benefit(s) provided by the PSOB Program. If no such benefits were provided, the certification must explain whether any survivors are eligible for a death benefit under the PSOB Program and, if so, whether death benefits have been sought under the PSOB Program.

(b) A representative seeking a death benefit under § 102.82(d) on behalf of a dependent requester younger than the age of 18 deemed an eligible survivor by the Secretary must submit, in addition to the documentation submitted under subpart F, the following:

(1) Documentation showing that the deceased smallpox vaccine recipient or vaccinia contact is survived by one or more dependents younger than the age of 18. Such documentation must show

the date of birth of all such dependents (e.g., copies of birth certificates);

(2) A written selection by each legal guardian, on behalf of all of the dependents described in paragraph (b)(1) of this section for whom he or she is the legal guardian, to receive proportional death benefits under the alternative calculation as described in § 102.82(d), in place of proportional benefits available under the standard calculation as described in § 102.82(c). Written selections are described in § 102.82(d)(1).

(3) Documentation showing that the requester is the legal guardian of all of the dependents described in paragraph (b)(1) of this section, as required under § 102.63(b). If multiple dependents have different legal guardians, the legal guardian of each dependent(s) must submit such documentation;

(4) Documentation showing the deceased smallpox vaccine recipient or vaccinia contact's gross employment income at the time the covered injury was sustained (e.g., the decedent's most recent Federal tax return or a pay stub from the time of the covered injury); and

(5) A description of all third-party payors that have paid for or that may be required to pay for the benefits described in § 102.82(d)(3)(A). This description must include the amount of such benefits that have been paid or that may be authorized to be paid in the future. If the representative knows of no such third-party payor, he or she must certify to that fact. If, at any time, the representative becomes aware that a third-party payor may have such an obligation, he or she must inform the Secretary within 10 business days of becoming aware of this information.

**§ 102.63 Documentation a representative filing on behalf of an eligible requester who is a minor or a legally incompetent adult must submit.**

Before benefits will be paid under by the Program to an eligible requester who is a minor or legally incompetent adult, his or her representative must submit, in addition to the documentation submitted under subpart F and under §§ 102.60–102.62, the following:

(a) Documentation showing that the requester is:

(1) A minor (e.g., birth certificate); or  
(2) A legally incompetent adult (e.g., court decree of incompetency); and

(b) Documentation showing that:

(1) In the case of a minor, the requester is the legal guardian of the minor (e.g., birth certificates for parents who are legal guardians or, for other legal guardians, a decree by a court of competent jurisdiction establishing the legal guardianship of a person other

than the minor's parents under applicable State law). If a minor has more than one legal guardian, this information is required only of one legal guardian; or

(2) In the case of a legally incompetent adult, a decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the requester's estate under applicable State law.

#### Subpart H—Secretarial Determinations

##### § 102.70 Determinations the Secretary must make before benefits can be paid.

(a) Before reviewing a Request Package, the Secretary will assign a Program number to the Request Package and so inform the requester (or his or her representative) in writing. All correspondence to the requester (or his or her representative) about a specific Request Package will be referenced by this Program number.

(b) Before the Secretary will pay benefits under this Program, he must determine that:

(1) The requester or his or her representative submitted a completed (to the fullest extent possible) and signed Request Form within the governing filing deadline;

(2) The requester meets the eligibility requirements set out in this part (including a determination that a covered injury was sustained); and

(3) The requester is entitled to receive benefits from the Program. In making this determination, the Secretary will decide the type(s) and amounts of benefits that will be paid to the requester.

(c) Once the Secretary has sufficient documentation to make an eligibility or benefits determination, he will make the decision in a timely manner.

##### § 102.71 Insufficient documentation for eligibility and benefits determinations.

In the event that there is insufficient documentation in the Request Package for the Secretary to make the applicable determinations under this part, the Secretary will notify the requester, or his or her representative. The requester will be given 60 calendar days from the date of the Secretary's notification to submit the required documentation. If the requester is unable to provide the additional documentation, he or she may write to the Secretary and explain the reason that the requested documentation is unavailable and the efforts the requester has taken to obtain the documents. The Secretary may accept such a letter in place of the required documentation or disapprove the request due to insufficient

documentation. If no documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the request. The Secretary also may require an authorization from the requester (or his or her representative) to try to obtain required documentation on his or her behalf.

##### § 102.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to conduct an evaluation of a requester's eligibility, he will begin the review to determine whether the requester is eligible. If the Secretary determines that the requester is not eligible, the Secretary will inform the requester (or his or her representative) in writing of the disapproval and the options available to the requester, including reconsideration.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, he will, after receiving documentation from the requester for a benefits determination, either calculate the amount and types of benefits, as described in subpart I of this part, or request additional documentation in order to calculate the benefits that can be paid (e.g., an Explanation of Benefits from the requester's insurance company if none was provided).

(c) *Additional documentation required.* At any time after a Request Form has been filed, the Secretary may direct a requester to supplement or amend the Request Package by providing additional information or documentation.

##### § 102.73 Approval of benefits.

When the Secretary has determined that benefits will be paid to a requester and has calculated the type and amount of such benefits, he will notify the requester (or his or her representative) in writing. The Secretary will make payments in accordance with § 102.83.

##### § 102.74 Disapproval of benefits.

(a) If the Secretary determines that a requester is not eligible for payments under the Program, the Secretary will disapprove the request and provide the requester, or his or her representative, with a written notice of the basis for the disapproval and the options available to the requester, including reconsideration.

(b) The Secretary may disapprove a request at any time, even before the requester has submitted required documentation (e.g., the Secretary may determine that a requester did not meet the filing deadline, even before required

documentation is submitted or reviewed).

#### Subpart I—Calculation and Payment of Benefits

##### § 102.80 Calculation of medical benefits.

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for those medical items and services that are reasonable and necessary to diagnose or treat a smallpox vaccine recipient or vaccinia contact's covered injury or its health complications, as described in § 102.31. The Secretary will consider and may rely upon benefits documentation submitted by the requester (e.g., bills, Explanation of Benefits, and cost-related documentation to support the expenses relating to the covered injury or its health complications), as required by § 102.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payor and only if no third-party payor had or has an obligation to provide such services or items to the requester, except as provided in § 103.83(c) and § 103.84. There are no caps on medical benefits that may be provided under the Program.

##### § 102.81 Calculation of benefits for lost employment income.

(a) *Primary calculation.* Benefits under this section may be paid for days of work lost as a result of a covered injury or its health complications if the smallpox vaccine recipient or vaccinia contact lost employment income for the lost work days. As described in § 102.32(c), days in which an individual used paid leave (including vacation and sick leave) for lost work days will not be considered days for which the individual lost employment income (unless the individual's employer restores the leave taken by putting the employee in the same position as if he or she had not used paid leave).

(1) The Secretary will calculate the rate of benefits to be paid for the lost work days based on the smallpox vaccine recipient or vaccinia contact's gross employment income, which includes income from self-employment, at the time he or she sustained the covered injury. The Secretary may not, except with respect to injured individuals who are minors, consider projected future earnings in this calculation.

(A) For a smallpox vaccine recipient or vaccinia contact with no dependents at the time the covered injury was sustained, the benefits are 66⅔% of the individual's gross employment income

at the time the covered injury was sustained.

(B) For a smallpox vaccine recipient or vaccinia contact with one or more dependents at the time the covered injury was sustained, the benefits are 75% of the individual's gross employment income at the time the covered injury was sustained; and

(2) In the case of a smallpox vaccine recipient or vaccinia contact who is a minor, the Secretary may consider the provisions of 5 U.S.C. 8113 (part of the statute authorizing the FECA Program), and any implementing regulations, in determining the amount of payments under this section and the circumstances under which such payments are reasonable and necessary.

(b) *Adjustment for inflation.* Benefits for lost employment income paid under the Program that represent future lost employment income will be adjusted annually to account for inflation.

(c) *Limitations on benefits paid.* The Secretary will reduce the benefits calculated under paragraphs (a) and (b) of this section, according to the limitations described in this paragraph:

(1) *Annual limitation.* The maximum amount that a requester can receive in any one year in benefits for lost employment income under this Program is \$50,000;

(2) *Lifetime limitation.* The maximum amount that a requester can receive during his or her lifetime in benefits for lost employment income under this Program is the amount of the death benefit calculated under the PSOB Program in the same fiscal year as the year in which this lifetime cap is reached. This amount is the maximum death benefit payable to survivors under this Program using the standard calculation described in § 102.82(c). However, this lifetime cap does not apply if the Secretary determines that the smallpox vaccine recipient or vaccinia contact has a covered injury (or injuries) meeting the definition of "disability" in section 216(i) of the Social Security Act, 42 U.S.C. 416(i); and

(3) *Number of lost work days.* A requester will be compensated for ten or more days of work lost if he or she lost employment income for those days as a result of the covered injury (or its health complications). If the number of days of lost employment income due to the covered injury (or its health complications) is fewer than ten, the Secretary will reduce the number of lost work days by 5 days. If the smallpox vaccine recipient or vaccinia contact lost employment income for a period of 5 days or fewer, no benefits for lost employment income will be paid. Lost

work days do not need to be consecutive. Partial days of lost employment income may be aggregated to calculate the total number of lost work days. The Secretary has the discretion to consider the reasonableness of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation.

(d) *Reductions for other coverage.* From the amount of benefits calculated under paragraphs (a), (b), and (c) of this section, the Secretary will make reductions:

(1) For all payments made, or expected to be made in the future, to the requester for compensation of lost employment income or disability or retirement benefits, by any third-party payor in relation to the covered injury or its health complications, consistent with § 102.32(b); and

(2) So that the total amount of benefits for lost employment income paid to a requester under this Program, together with the total amounts paid (or payable) by third-party payors, as described in paragraph (d)(1) of this section, does not exceed 66⅔% (or 75%, if the smallpox vaccine recipient or vaccinia contact had at least one dependent at the time the covered injury was sustained) of his or her employment income at the time of the covered injury for the lost work days. If a requester receives a lump-sum payment from any third-party payor, under any obligation described in paragraph (d)(1) of this section, the Secretary will deem such a payment to be received over a period of years, rather than in a single year. The Secretary has discretion as to how to apportion such payments over multiple years; and

(e) *Termination of payments.* The Secretary will not pay benefits for lost employment income after the requester reaches the age of 65.

#### § 102.82 Calculation of death benefits.

(a) *Definitions.* For purposes of this section:

(1) *Alternative calculation* means the calculation used under paragraph (d) of this section for the death benefit available to dependents.

(2) *Deceased person* means an otherwise eligible deceased smallpox vaccine recipient or vaccinia contact; and

(3) *Dependent* means a person whom the Internal Revenue Service would have considered the deceased person's dependent at the time the covered injury was sustained, and who is younger than the age of 18 at the time of filing the Request Form.

(4) *Standard calculation* means the calculation used under paragraph (c) of

this section for the death benefit available to all eligible survivors (other than dependents who do not meet another category of eligible survivors, such as surviving eligible children).

(b) *General.* (1) If the legal guardian(s) of dependents younger than 18 years of age does not file a written selection to receive death benefits under the alternative calculation, as described in paragraph (d)(1) of this section, or if the Secretary does not approve such a selection, the Secretary will pay proportionate death benefits under the standard calculation to all of the eligible survivors with priority to receive death benefits under the standard calculation, as described in § 102.11(b).

(2) If the Secretary approves a written selection to receive benefits under the alternative calculation, as described in paragraph (d)(1) of this section:

(A) If no other eligible survivors are of equal priority to receive death benefits, the Secretary will pay a death benefit in an amount calculated under the alternative calculation to the aggregate of the dependents on whose behalf the election was filed; and

(B) If other eligible survivors are of equal priority to receive death benefits as the dependents receiving death benefits under the alternative calculation, the Secretary will pay the other eligible survivors a proportionate amount of the death benefit available and calculated under the standard calculation. In such circumstances, the Secretary will pay the aggregate of the dependents receiving a death benefit under the alternative calculation a proportionate share of the benefits available under that calculation (in place of the proportionate share of the death benefit that would be available under the standard calculation). For example, if a deceased smallpox vaccine recipient is survived by a dependent 10-year old child and a spouse who is not the child's legal guardian (e.g., the dependent child's parents were the deceased person and his or her former spouse), the surviving spouse would be able to receive his or her share of the death benefit under the standard calculation, and the dependent child's legal guardian, on behalf of the minor, would receive either the child's proportionate share of the death benefit under the standard calculation or the child's proportionate share of the death benefit available under the alternative calculation (if the legal guardian filed a written selection for such a death benefit).

(c) *Standard calculation of death benefits.* (1) The maximum death benefit available under the standard calculation of death benefits is the amount of the

comparable death benefit calculated under the PSOB Program in the same fiscal year as the year in which the death benefit under the standard calculation is paid under this Program (without regard to any reduction under the PSOB Program attributable to a limitation in appropriations), reduced by the total amount of benefits for lost employment income paid under this Program to the deceased person during his or her lifetime and to his or her estate after death.

(2) No death benefit will be paid under the standard calculation if a death benefit has been paid, or if survivors are eligible to receive a death benefit, under the PSOB Program with respect to the deceased person.

(3) No death benefit will be paid under the standard calculation if a disability benefit has been paid under the PSOB Program with respect to the deceased person. However, if the PSOB Program disability benefit paid was reduced because of a limitation on appropriations, a death benefit will be available under the standard calculation to the extent necessary to ensure that the total amount of disability benefits paid under the PSOB Program, together with the amount of death benefits paid under the standard calculation, equals the amount of the death benefit described in paragraph (c)(1) of this section.

(4) Death benefits will be paid under the standard calculation in a lump sum.

(d) *Alternative calculation of death benefits available to surviving dependents younger than the age of 18.* If a deceased smallpox vaccine recipient or vaccinia contact had at least one dependent who is younger than the age of 18 (and will be younger than the age of 18 at the time of the payment), the legal guardian(s) of all such dependents may request benefits under the alternative calculation described in this paragraph. To receive such a benefit, the legal guardian, on behalf of all such dependents for whom he or she is the legal guardian, must file a selection to receive benefits under the alternative calculation, as described in paragraph (d)(1) of this section. If multiple dependents have different legal guardians, each legal guardian is responsible for requesting benefits under the standard calculation or for filing a selection for a death benefit under the alternative calculation. If a single dependent has more than one legal guardian, one legal guardian may file the selection. Payments made under the alternative calculation will be made to the legal guardian(s) of all of the dependents on behalf of all of those

dependents until they reach the age of 18.

(1) *Selection of benefits under alternative calculation.* Before a payment of a death benefit will be approved under the alternative calculation, the legal guardian(s) of the dependents for whom he or she is the legal guardian must file a written selection, on behalf of all such dependents, to receive a death benefit under the alternative calculation. If such a selection is approved by the Secretary, these dependents will be paid a proportionate share of the death benefit under the alternative calculation in place of the proportionate share of benefits that would otherwise be available to them under the standard calculation.

(2) *Amount of payments.* The maximum death benefit available under this paragraph is 75% of the deceased person's income (including income from self-employment) at the time he or she sustained the covered injury that resulted in death, adjusted to account for inflation (as appropriate), except as follows:

(A) The maximum payment of death benefits that may be made on behalf of the aggregate of the dependents in any one year is \$50,000;

(B) All payments made under this paragraph will stop once the youngest of the dependents reaches the age of 18.

(3) *Reductions for other coverage.* The total amount of death benefits provided under the alternative calculation will be reduced so that the total amount of payments made (or expected to be made) under obligations described in paragraph (d)(3)(A) of this section, together with the death benefits paid under the alternative calculation, is not greater than the amount of payments described in paragraph (d)(2) of this section. In other words, the total amount of death benefits paid to dependents under the alternative calculation may be reduced if third-party payors have paid (or are expected to pay) for certain benefits so that such dependents will receive a total sum (combining the death benefit paid under the alternative calculation and the actual and expected benefits paid for by third-party payors) that is not greater than the death benefit that would be available under the alternative calculation if no third-party payor existed to pay such benefits.

(A) The amount of death benefits paid under the alternative calculation will be reduced for all payments made, or expected to be made in the future, by any third-party payor for:

(i) Compensation for the deceased person's loss of employment income on

behalf of the dependents or their legal guardian(s);

(ii) Disability, retirement, or death benefits in relation to the deceased person (including, but not limited to, death and disability benefits under the PSOB Program) on behalf of the dependents or their legal guardian(s); and

(iii) Life insurance benefits on behalf of the dependents.

(B) In calculating such reductions, the Secretary will deem any lump-sum payment made by a third-party payor under any obligation described in paragraph (d)(3)(A) of this section, as received over a period of years, rather than in a single year. The Secretary has discretion as to how to apportion such payments over multiple years.

(4) *Timing of payments.* Payments made under this paragraph will be made on an annual basis, beginning at the time of the initial payment, to the legal guardian(s) on behalf of the aggregate of the dependents receiving the payment. In the year in which the youngest dependent reaches the age of 18, payments under this section will be paid on a pro rata basis for the period of time before that dependent reaches the age of 18. Once a dependent reaches the age of 18, the payments under this alternative calculation will no longer be made on his or her behalf. Because payments under the alternative calculation are to be made on behalf of dependents who are younger than the age of 18, if a dependent meets this requirement at the time of filing of the Request Form, but reaches the age of 18 (or is older than 18 years of age) at the time of the initial payment, no payment will be made to the dependent's legal guardian on his or her behalf under the alternative calculation.

#### **§ 102.83 Payment of all benefits.**

(a) The Secretary may pay any benefits under this Program through lump-sum payments. If the Secretary determines that there is a reasonable likelihood that the payments of medical benefits, benefits for lost employment income, or death benefits paid under the alternative calculation (described in § 102.82(d)) will be required for a period in excess of one year from the date the Secretary determines the requester is eligible for such benefits, the Secretary may make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total amount of benefits that

the requester is eligible to receive under §§ 102.80, 102.81, and 102.82(d).

(b) Lump sum payments will be made through an electronic funds transfer to an account of the requester. However, if the requester is a minor, the payment will be made to the account of his or her legal guardian on behalf of the minor. In accepting such payments, the legal guardian of a minor requester is obliged to use the funds for the benefit of the minor and to take any actions necessary to comply with state law requirements pertaining to such payments. If the requester is a legally incompetent adult, the legal guardian must establish a guardianship or conservatorship of the estate account with court oversight, in accordance with State law, and payment will be made to that account.

(c) The Secretary may, at his discretion, make interim payments of benefits under this Program, even before he makes a final determination as to the total type and total amount of benefits that will be paid. The Secretary may, for example, make an interim payment of medical benefits that have been calculated before a final determination on benefits for lost employment income is completed, or of past medical benefits that have been calculated before a final calculation of future medical benefits is completed. The Secretary may, in his discretion, make an interim payment even before a final eligibility or benefits determination is made (e.g., if a piece of documentation has not been obtained because a person with a severe vaccine-related injury is hospitalized, but all other documentation is consistent with the requester meeting the eligibility requirements). If such a requester's documentation is incomplete, the requester must submit the required documentation within the time-frame determined by the requester. Such a requester must agree that he or she will be obliged to repay the Secretary such benefits in the event that such payments are later determined to be inappropriate. Any payments made on an interim basis will not entitle a requester to seek reconsideration of the Secretary's decision on these benefits until the Secretary makes a complete benefits determination.

**§ 102.84 The Secretary's right to recover benefits paid under this program from third-party payors.**

Upon payment of benefits under this program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payor with a legal or contractual obligation to pay for (or provide) such benefits and may recover from such third-party payor(s) the

amount of benefits paid up to the amount of benefits the third-party payor has or had an obligation to pay for (or provide). In other words, the Secretary may pay benefits before the requester receives a payment from a third-party payor in specific circumstances. In those circumstances, the Secretary has a right to be reimbursed by the third-party payor. The circumstances in which the Secretary may assert this right include those in which the Secretary pays benefits under this Program to a requester before a final decision is made that a third-party payor has an obligation to pay such benefits to the requester. Requesters receiving benefits under this Program (or their representatives) shall assist the Secretary in recovering such benefits. In the event that a requester receives a benefit from a third-party payor after receiving the same type of benefits from the Secretary under this Program, the Secretary has a right to recover the amount of the benefits awarded from the requester.

**Subpart J—Reconsideration of the Secretary's Determinations**

**§ 102.90 Reconsideration of the Secretary's eligibility and benefits determinations.**

(a) *Right of reconsideration.* A requester has the right to seek reconsideration of the Secretary's determination that he or she is not eligible for payment. In addition, a requester who asserts that the amount of the benefits paid by the Secretary (or the fact that certain benefits were not paid or payable) is incorrect may also seek reconsideration. Letters seeking reconsideration must be in writing, describe the reason(s) why the decision should be reconsidered, and be postmarked within 60 calendar days of the date of the Secretary's decision on the request. Because no new documentation will be considered in the reconsideration process, the letter seeking reconsideration may not include or refer to any documentation that was not before the Secretary at the time of his initial determination.

(b) *Letters seeking reconsideration.* A requester, or his or her representative, may send a letter seeking reconsideration through the U.S. Postal Service, commercial carrier, or a private courier service. The Secretary will not accept letters seeking reconsideration electronically or by hand-delivery.

(1) Letters sent through the U.S. Postal Service must be sent to the Associate Administrator, Special Programs Bureau, Health Resources and Services Administration, 5600 Fishers Lane,

Room 16C-17, Rockville, Maryland 20857.

(2) Letters sent through a commercial carrier or private courier service must be sent to the Associate Administrator, Special Programs Bureau, Health Resources and Services Administration, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814.

(c) *Reconsideration process.* When the Associate Administrator of the Special Programs Bureau (the Associate Administrator), receives a letter seeking reconsideration, a qualified panel will be convened, independent of the Program, to review the Secretary's initial determination. The panel will base its recommendation on the documentation before the Secretary when the initial determination(s) was made. The panel will perform its own review and make its own findings, which will be submitted to the Associate Administrator. The Associate Administrator will then review the panel's recommendation(s) and make a final determination, which will be sent to the requester (or his or her representative). This will be the Secretary's final action on the letter seeking reconsideration and will be considered the Secretary's final determination on the request. Requesters may not seek review of a decision made on reconsideration.

**§ 102.91 Secretary's review authority.**

Under section 262(f)(1) of the Public Health Service Act (42 U.S.C. 239a(f)(1)), the Secretary may, at any time, review on his own motion or on application, any determination made under this part (including, but not limited to, determinations concerning eligibility, entitlement to benefits, and the calculation and payment of benefits under the Program). Upon review of such a determination, the Secretary may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.

**§ 102.92 No additional judicial or administrative review of determinations made under this part.**

Under section 262(f)(2) of the Public Health Service Act (42 U.S.C. 239a(f)(2)), no further judicial review of the Secretary's actions under this part (including, but not limited to, eligibility determinations, the calculation of benefits, and determinations about the method of payment of benefits) is permitted. In addition, no further administrative review of the Secretary's actions under this part is permitted

unless the President specifically directs otherwise.

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