

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