

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