

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

42 CFR Part 110

RIN # 0906-AA83

Countermeasures Injury Compensation Program (CICP):

Administrative Implementation, Interim Final Rule

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Interim final rule with request for comments.

SUMMARY: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to establish the Countermeasures Injury Compensation Program (CICP or Program). The Department of Health and Human Services (HHS) is issuing this interim final rule with request for comments in order to establish administrative policies, procedures, and requirements for the CICP. This Program is designed to provide benefits to certain persons who sustain serious physical injuries or death as a direct result of administration or use of covered countermeasures identified by the Secretary in declarations issued under the PREP Act. In addition, the Secretary may provide death benefits to certain survivors of individuals who died as the direct result of such covered injuries or their health complications. The Secretary is seeking public comments on this interim final rule.

DATES: This regulation is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Written comments must be submitted on or before [INSERT DATE 60 DATES AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The Secretary

will consider the comments received and will decide whether to amend the current procedures and requirements based on such comments.

ADDRESS and Mode of Transmission for Comments: You may submit comments in one of three ways, as listed below. The first is the preferred method. Please submit your comments in only *one* of these ways, so that no duplicates are received.

1. ***Federal eRulemaking Portal.*** You may submit comments electronically to <http://www.regulations.gov>. Click on the link “Submit electronic comments on HRSA regulations with an open comment period.” Submit your actual comments as an attachment to your message or cover letter. (Attachments should be in Microsoft Word or WordPerfect; however, we prefer Microsoft Word.)
2. ***By regular, express or overnight mail.*** You may mail written comments to the following address only: Health Resources and Services Administration, Department of Health and Human Services, Attention: HRSA Regulations Officer, Parklawn Building Rm. 14A-11, 5600 Fishers Lane, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. ***Delivery by hand (in person or by courier).*** If you prefer, you may deliver your written comments before the close of the comment period to the same address: Parklawn Building Room 14A-11, 5600 Fishers Lane, Rockville, MD 20857. Please call in advance to schedule your arrival with one of our HRSA Regulations Office staff members at telephone number (301) 443-1785.

Because of staffing and resource limitations, and to ensure that no comments are misplaced, we cannot accept comments by facsimile (FAX) transmission.

In commenting, please refer to file code [# HRSA–XXXX]. Comments received on a timely

basis will be available for public inspection as they are received, beginning approximately 3 weeks after publication of this Notice, in Room 14-05 of the Health Resources and Services Administration's offices at 5600 Fishers Lane, Rockville, MD., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 301-443-1785).

FOR FURTHER INFORMATION CONTACT: Dr. Vito Caserta, Director, Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857. Phone calls can be directed to (888) ASK-HRSA (275-4772). This is a toll-free number.

SUPPLEMENTARY INFORMATION:

Background

This regulation administratively establishes the compensation program authorized by the Public Readiness and Emergency Preparedness Act (the PREP Act) which added new authorities under sections 319F-3 and 319F-4 of the Public Health Service Act, as amended (PHS Act) (42 U.S.C. §§ 247d-6d, 247d-6e). The PREP Act, which was enacted as part of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act of 2006 (Public Law 109-148) on December 30, 2005, confers broad liability protections to covered persons and authorizes compensation to eligible individuals who sustain serious physical injuries or deaths as the direct result of the administration or use of a covered countermeasure for a disease, condition, or threat that the Secretary of Health and Human Services (the Secretary) determines either constitutes a current public health emergency, or there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is identified in a declaration issued by the Secretary under the PREP Act.

Both the liability protections and the compensation authorized under the PREP Act are invoked by declarations issued by the Secretary (hereinafter PREP Act declarations or declarations) (section 319F-3(b) of the PHS Act (42 U.S.C. §247d-6d(b)). Through the issuance of such PREP Act declarations, the Secretary makes a determination that a disease, condition, or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. In such declarations, the Secretary recommends targeted liability immunity for persons or entities involved in the manufacture, testing, development, distribution, dispensing, administration, and/or use of a covered countermeasure for the disease, threat, or condition specified. Each Secretarial declaration specifies, for each covered countermeasure identified in the declaration:

- (a) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the covered countermeasure;
- (b) the period or periods during which the liability protections are in effect (for example, from a certain date through a future date, or other descriptions of events that would trigger the application of the liability protections);
- (c) the population or populations for whom the Secretary recommends the administration or use of the covered countermeasure (for example, the entire population during a pandemic period); and
- (d) the geographic area or areas for which the liability protections are in effect (*e.g.*, no geographic limitation, a certain region of the United States).

In addition, the Secretary can provide whether the liability protections are only available for specified distribution methods (for example, the liability protections shall only be in effect if the countermeasures are obtained through a voluntary means of distribution). The Secretary may change any component of a declaration by amendment.

The Secretary publishes all PREP Act declarations, and amendments to such declarations, in the Federal Register. In addition, they are generally posted on the Department's web site at <http://www.hhs.gov/disasters/discussion/planners/prepact/> and on the Program's web site at <http://www.hrsa.gov/countermeasurescomp/>. As of April 2010, the Secretary had published declarations with respect to the following countermeasures: (1) pandemic influenza vaccines (including, but not limited to the influenza A H1N1 2009 monovalent vaccine which will be hereafter referred to as the 2009 H1N1 vaccine); (2) anthrax countermeasures; (3) botulism countermeasures; (4) the influenza antiviral drugs Tamiflu® and Relenza® when used for pandemic purposes; (5) smallpox countermeasures; (6) acute radiation syndrome countermeasures; (7) pandemic influenza diagnostics, personal respiratory devices, and respiratory support devices; and (8) the influenza antiviral drug peramivir when used to treat pandemic H1N1 2009 influenza (which will be hereafter referred to as 2009 H1N1). Several of these declarations have been amended, some on multiple occasions.

“Covered countermeasure” is a term of art defined in the PREP Act and includes three categories (section 319F-3(i)(1) of the PHS Act (42 U.S.C. § 247d-6d(i)(1)). The first category, consisting of “qualified pandemic or epidemic product[s],” is defined in section 319F-3(i)(7) of the PHS Act (42 U.S.C. § 247d-6d(i)(7)). This category includes products (drugs, biological products, and devices) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or to limit the harm such pandemic or epidemic might otherwise cause. The category also extends to products used to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a “qualified pandemic or epidemic product.” In order to qualify, a drug, biological product, or device must be: (1) approved or cleared under the Federal Food, Drug, and Cosmetic Act

(FFDCA) or licensed under the PHS Act; (2) the subject of research for possible use and subject to an exemption under sections 505(i) or 520(g) of the FFDCA; or (3) covered under an emergency use authorization (in accordance with section 564 of the FFDCA).

The second category includes “security countermeasure[s].” A security countermeasure, defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. §247d-6b(c)(1)(B)), is a drug, biological product, or device that the Secretary determines: (1) is a priority to diagnose, mitigate, prevent, or treat harm either from an agent identified as a material threat or from a condition that may result in injuries or deaths and may be caused by administering a drug, biological product, or device against such an agent; (2) is a necessary countermeasure; and (3) is approved or cleared under the FFDCA or licensed under the PHS Act or will likely be approved, cleared or licensed within eight years or is authorized for emergency use under section 564 of the FFDCA.

The final category consists of products subject to emergency use authorizations. This category extends to drugs (as defined in section 201(g)(1) of the FFDCA, 21 U.S.C. § 321(g)(1)), biological products (as defined in section 351(i) of the PHS Act (42 U.S.C. § 262), or devices (as defined in section 201(h) of the FFDCA, 21 U.S.C. § 321(h)) that are authorized for emergency use in accordance with section 564 of the FFDCA.

In order to be eligible for the liability protections of the PREP Act or to receive benefits under the compensation provisions of the PREP Act, a covered countermeasure must meet one of these three categories and must also be identified by the Secretary in a PREP Act declaration. As explained above, the liability protections afforded by the PREP Act are tied to Secretarial declarations. The PREP Act’s liability protections are broad, covering, for example, the manufacture, testing, development, distribution, dispensing, administration or use of the designated covered countermeasure (absent willful misconduct as defined in section 319F-3(c)

(1) of the PHS Act (42 USC § 247d-6d(c)(1)). The immunity from suit afforded by the PREP Act applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure[s] (section 319F-3(a)(2)(B) of the PHS Act (42 U.S.C. § 247d-6d(a)(2)(B))). For more information about the liability protections afforded to covered persons under the PREP Act, questions and answers are available on the Department's web site at <http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterrorism/medication-vaccine-qa.html> and <http://www.hhs.gov/disasters/discussion/planners/prepact/prepact-h1n1.html>.

In addition to establishing the PREP Act's liability protections for covered persons, the PREP Act authorizes the Secretary to establish a program to provide compensation to eligible individuals for certain covered injuries sustained as the direct result of the administration or use of a covered countermeasure identified in a PREP Act declaration. The Secretary delegated the authority to operate the compensation program described in section 319F-4 of the PHS Act (42 U.S.C. § 247d-6e) to the Administrator of the Health Resources and Services Administration (HRSA) on November 8, 2006. Pursuant to this delegation of authority, HRSA established and administers the Countermeasures Injury Compensation Program (hereinafter CICIP or Program).

Under the CICIP, certain persons may be eligible for benefits for covered injuries, described below, sustained as a direct result of the administration or use of covered countermeasures. The PREP Act stipulates that the CICIP will follow, with very limited exceptions, the Smallpox Vaccine Injury Compensation Program (SVICP) for eligibility and

compensation determinations (section 319F-4(b)(4) of the PHS Act (42 U.S.C. § 247d-6e(b)(4)). In addition, the elements of compensation are almost identical to those available under the SVICP (section 319F-4(b)(2) of the PHS Act (42 U.S.C. § 247d-6e(b)(2)). The SVICP was established under the Smallpox Emergency Personnel Protection Act of 2003 (SEPPA) and its implementing regulations are available at 42 CFR Part 102. Specifically, the PREP Act provides that (with limited exceptions) the CICP is to follow the SEPPA, the SVICP regulations implementing the SEPPA, and such additional or alternate regulations as the Secretary may promulgate for purposes of this section (section 319F-4(b)(4) of the PHS Act (42 U.S.C. § 247d-6e(b)(4)). The Secretary is issuing this interim final rule under that authority.

As authorized under the PREP Act, the Secretary is herein, at 42 CFR part 110, establishing the procedures and requirements governing the CICP. As explained below, the Secretary is issuing this regulation as an interim final rule, to be effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. However, the Secretary is seeking public comments on these procedures and requirements and may change provisions of this regulation upon review of the comments received.

Summary of the Regulation

Summary of Available Benefits (§ 110.2)

The benefits available under this Program are medical benefits, benefits for lost employment income, and survivor death benefits. Medical benefits are described more fully in § 110.31 and include payment or reimbursement for medical services and items that the Secretary determines are reasonable and necessary to diagnose or treat a covered injury and to diagnose, treat, or prevent its health complications. Benefits for lost employment income are described more fully in § 110.32 and cover lost employment income incurred as a result of a covered injury

or its health complications. Death benefits are described in § 110.33 and provide payments to survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury. As described in § 110.33, death benefits are available under standard or alternative calculations depending upon the eligible survivors.

As explained in § 110.2(b), the PREP Act, based upon provisions included in the SEPPA, establishes that the government generally is a secondary payer for benefits available under the Program. For example, death benefits paid under the alternative calculation in § 110.82(c) are secondary to death and disability benefits under the Public Safety Officers' Benefits (PSOB) Program (a program within the United States Department of Justice that provides payments to public safety officers and their survivors, including death benefits for officers killed in the line of duty).

Benefits under the Program usually will only be paid after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits. Requesters generally must provide the names of all other third party payers that have already provided benefits, that are expected to do so in the future, or that may have a legal or contractual obligation to do so. These payers include, but are not limited to: insurance companies, workers' compensation programs, the Federal Employees' Compensation Act (FECA) Program, military treatment facilities (MTFs), the Department of Veterans Affairs, or the PSOB Program. If such a third-party payer 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 so that the requester does not have unreimbursed out-of-pocket expenses. For example, if a requester determined to be eligible for medical benefits incurred \$10,000 in reasonable and necessary medical expenses resulting from a covered

injury and the requester's health insurance company (a third-party payer) has paid \$5,000 for the covered medical benefits and services, the Program would reimburse the requester \$5,000 (representing the amount the requester is entitled to under this Program, reduced by the amount paid or payable by third-party payers). As explained later, upon payment of benefits under the Program, the Secretary will be subrogated to the rights of the requester and may assert a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

Eligible Requesters (§ 110.10)

There are three categories of eligible requesters under the Program: (1) injured countermeasure recipients; (2) survivors of deceased injured countermeasure recipients who died as a direct result of the administration or use of a covered countermeasure; and (3) executors or administrators on behalf of the estates of deceased injured countermeasure recipients (regardless of their cause of death).

Injured Countermeasure Recipients

The first category of requesters, an "injured countermeasure recipient" is defined in § 110.3(n) as an individual:

- (1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:
 - (A) meets the specifications of the pertinent declaration; or
 - (B) is administered or uses a covered countermeasure in a good faith belief that he or she meets the specifications of the pertinent declaration; and
- (2) sustained a covered injury as defined in § 110.3(g).

(3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(A) or (1)(B), any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

Thus, the eligibility requirements for injured countermeasure recipients may vary based on the terms of the PREP Act declaration issued with respect to the particular covered countermeasure. For example, all of the declarations issued to date, which are subject to change, include specific limitations in Category I, entitled "Covered Countermeasures." The amended PREP Act declaration for pandemic influenza vaccines specifies that the liability immunity afforded under the PREP Act "shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding for vaccines against pandemic influenza A viruses with pandemic potential used and administered in accordance with this Declaration, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the pandemic countermeasures following a declaration of an emergency, as defined in section IX below" (74 Fed. Reg. 51153 (Oct. 5, 2009)). This document defines an Authority Having Jurisdiction as "the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere or authority." *Id.*

Thus, the immunity protections (and the benefits available under the CICP) are contingent upon either requirement (and not necessarily both) being satisfied. With respect to

each requester who received a covered countermeasure identified in a declaration with such language, the Secretary will have to consider whether the administration or use of a covered countermeasure met either of the requirements set forth above or whether there was a good faith belief of such at the time of the administration or use in order to determine whether the person identified as an injured countermeasure recipient meets the requirements of § 110.3(n)(1). In the case of 2009 H1N1 vaccines, this inquiry will generally be simple, given that all such vaccines distributed in the United States were purchased under contract by the Federal Government (satisfying the first requirement quoted above).

The amended PREP Act declaration for the influenza antivirals Tamiflu® and Relenza® contains similar limitations to those described above in its section entitled “Covered Countermeasures.” Specifically, the amended PREP Act declaration provides that the liability immunity afforded under the PREP Act “shall only be in effect with respect to: (1) Present or future Federal contracts, cooperative agreements, grants, interagency agreements, or memoranda of understanding involving countermeasures that are used and administered in accordance with this declaration, and (2) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasure following a declaration of an emergency, as defined in section IX below” (73 Fed. Reg. 61861 (Oct. 17, 2008), amended by 74 Fed. Reg. 29213 (June 19, 2009)). The declaration, like other PREP Act declarations, goes on to define “the Authority Having Jurisdiction,” and the “Declaration of Emergency.” Many administrations or uses of pandemic influenza antivirals in the current 2009 H1N1 outbreak will certainly meet the first requirement (*e.g.*, antivirals from the Strategic National Stockpile are under Federal contracts). A more complicated analysis may be required with respect to other administrations or uses to

determine whether the alternate requirement (the Authority Having Jurisdiction requirement) was satisfied in particular circumstances. In order for the Authority Having Jurisdiction requirement to apply, the authorized activities must follow a declaration of emergency, as defined in the applicable declaration. With respect to the declaration for Tamiflu® and Relenza®, a “Declaration of Emergency” is defined as “[a] declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use pandemic countermeasures, with the exception of a Federal declaration in support of an emergency use authorization under section 564 of the FFDCA unless such declaration specifies otherwise” (73 Fed. Reg. at 61863, section IX (definitions)). The same declaration defines the “Authority Having Jurisdiction” as “the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.*, city, county, tribal, State, or Federal boundary lines) or functional (*e.g.*, law enforcement, public health) range or sphere of authority.” *Id.* Thus, the Authority Having Jurisdiction can vary depending upon the circumstances. The Secretary, in an amendment to the PREP Act declaration for the influenza antivirals Tamiflu® and Relenza® for pandemic use, shared her determination that the risk of the spread of 2009 H1N1 viruses and resulting disease constitutes a public health emergency (74 Fed. Reg. 29213 (June 19, 2009), amending 73 Fed. Reg. 61861 (Oct. 17, 2008)). Prior to the issuance of the PREP Act Declaration, the Acting Secretary, pursuant to the authority vested in him under section 319 of the Public Health Service Act, 42 U.S.C § 247d , issued a determination that a public health emergency existed nationwide involving H1N1 influenza that affected or has significant potential to affect national security. This determination was subsequently renewed by the current Secretary. Thus, with respect to covered countermeasures used in connection with the 2009 H1N1 virus, the Secretary has issued

a declaration of emergency sufficient to invoke the “Authority Having Jurisdiction” requirement in declarations published to date.

Although the Authority Having Jurisdiction requirement was intentionally worded broadly to account for the complexities of our national public health and emergency response systems (in which the Federal Government, States, localities, tribes, and the private sector play important roles), the Secretary wishes to provide some additional guidance to enable individuals who have been administered or used covered countermeasures to assess their potential eligibility for CICIP benefits as injured countermeasure recipients. In the Secretary’s view, activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the covered countermeasure will apply primarily in two contexts. Under the first scenario, authorized activities would include activities associated with the administration or use of covered countermeasures that were prescribed, administered, delivered, distributed, or dispensed by healthcare providers and others specifically authorized to do so under an agreement, memorandum of understanding, standard operating procedure, or other formal arrangement with an Authority Having Jurisdiction following the declaration of an emergency. In this way, the Authority Having Jurisdiction requirement would extend to individuals receiving medical care from private healthcare providers and institutions provided that the provider or institution is charged, through some sort of formal arrangement, by an Authority Having Jurisdiction with carrying out such activities as part of the public sector’s response.

Under the second scenario, activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction would include covered countermeasures administered or used in accordance with the written recommendations of an Authority Having

Jurisdiction following the declaration of an emergency. For example, if a local public health agency recommends that all persons with a certain high-risk condition who contract the 2009 H1N1 virus receive a particular course of treatment with an influenza antiviral identified in a PREP Act declaration following the declaration of emergency for the associated disease, then individuals who use such medications based on their doctors' compliance with such recommendations would qualify as activities authorized by the Authority Having Jurisdiction. Likewise, the Centers for Disease Control and Prevention (CDC) issued interim recommendations for the use of influenza antivirals for pandemic purposes. See e.g., "Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season" (available at <http://www.cdc.gov/H1N1flu/recommendations.htm>). If an individual used an influenza antiviral for pandemic purposes covered by a PREP Act declaration because his or her physician prescribed the covered countermeasure in accordance with the CDC's recommendations, then such use would meet the Authority Having Jurisdiction requirement because the physician's actions would constitute activities authorized by the Authority Having Jurisdiction (in this case, the CDC). Given the complexity of the health care delivery system and the numerous and diverse products already identified as covered countermeasures in PREP Act declarations, an analysis of whether particular specifications included in declarations will necessarily be declaration-specific and fact-specific. The Secretary notes that in certain cases, a patient being administered or using a covered countermeasure as a result of a healthcare provider's independent medical judgment, and not because the patient necessarily falls within a targeted group identified in an Authority Having Jurisdiction's recommendations, may qualify as an activity authorized by an Authority Having Jurisdiction because recommendations issued by

such authorities often take into account the need for healthcare providers to use independent clinical judgment with respect to the use or administration of covered countermeasures with respect to each patient. The Secretary does not wish to interfere with such independent clinical judgments.

Although this discussion of the Authority Having Jurisdiction requirement used in declarations to date is intended to assist potential requesters with the CICP, whether a particular recipient was administered or used a covered countermeasure in accordance with a particular PREP Act declaration will be dependent on the language included in the pertinent declaration, as well as the specific circumstances involved.

Administrations and Uses in Pregnant Women

Section 110.3(n)(3) addresses certain circumstances in which a pregnant woman is administered or uses a covered countermeasure. This provision applies to women when their administration or use of a covered countermeasure satisfies all of the terms of a PREP Act declaration (or if there was good faith belief of such). Thus, it applies to women who meet the definition of an injured countermeasure recipient under § 110.3(n) themselves, except that the pregnant women need not suffer a covered injury as required by § 110.3(n)(2). As provided for in § 110.3(n)(3), a child can qualify as an injured countermeasure recipient if the child survives birth, and is born with, or later sustains, a covered injury as the direct result of the mother's administration or use of a covered countermeasure during pregnancy. Such a child's eligibility for compensation under the Program is dependent upon the mother being administered, or using, a covered countermeasure under the terms of a declaration (or based on a good faith belief of such) and upon the child sustaining a covered injury as a result (regardless of whether the mother sustained a covered injury). Absent such a clarification, and in light of the breadth of the PREP

Act's liability protections (see *e.g.*, section 319F-3(a)(1)-(2)), such a child might be barred from pursuing litigation against a covered person (*e.g.*, a vaccine manufacturer) for an allegedly related injury (absent willful misconduct) without being afforded compensation otherwise available under the CICP. This is not the Secretary's intention. Eligibility of children for compensation under this Program does not depend upon whether the covered person (*e.g.*, doctor administering the vaccine) or the mother knew that she was pregnant at the time the covered countermeasure was administered or used.

Other Requesters

The second category of requesters, survivors of a deceased injured countermeasure recipient, is defined in § 110.3(bb) and described in § 110.11. Categories of eligible survivors and the priority of such survivors to receive benefits from the Program are discussed below in relation to § 110.33, which addresses death benefits (the only type of benefit survivors are eligible to receive).

The third category of requesters encompasses the estates of deceased injured countermeasure recipients, through their executors or administrators. These are individuals who are authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law. Estates of deceased injured countermeasure recipients are not eligible for death benefits, but they may be able to receive the medical and/or lost employment income benefits which the injured countermeasure recipient would have been paid by the Program prior to death, but had not received in full during his or her lifetime.

Members of the Uniformed Services and Eligibility for Benefits under the CICP.

Members of the Uniformed Services may be eligible for benefits under the CICP. The term Uniformed Services means the armed forces, the Commissioned Corps of the National

Oceanic and Atmospheric Administration and the Commissioned Corps of the Public Health Service. Such individuals are subject to the same eligibility requirements as civilians. The fact that they are members of the military or a Uniformed Service does not preclude them from receiving benefits under the CICIP if they are otherwise eligible. However, given that the CICIP is the payer of last resort (including after any medical care, lost wages, or other benefits provided by the United States Government or other third-party payers), the amount of benefits available under the CICIP may be minimal because of the benefits they are entitled to by virtue of their status as members of the Uniformed Services.

Territorial Limitations

As described in § 110.3(f) setting forth the definition of a covered countermeasure, in order for benefits to be available under the CICIP, the administration or use of the covered countermeasure must have occurred: (1) within a State (as defined in § 110.3(bb)), (2) otherwise within the territory of the United States; or (3) in a place over which the United States has sovereignty or some measure of legislative control. The requirement set forth in § 110.3(f) is based on the Secretary's conclusion that there is no "clear evidence of congressional intent" for the PREP Act's compensation provisions to apply extraterritorially (*Smith v. United States*, 507 U.S. 197, 204 (1993)). As explained in detail below, the primary consequence of this conclusion is that otherwise eligible individuals cannot receive benefits under the CICIP if the administration or use of covered countermeasures that allegedly gave rise to their injuries took place outside the territory or the territorial jurisdiction of the United States.

The Supreme Court of the United States has stated the "longstanding principle of American law that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States" (*Equal Employment Opportunity*

Commission v. Arabian American Oil Co. (Aramco), 499 U.S. 244, 248 (1991) (no clearly expressed congressional intent to apply Title VII extraterritorially) (superseded by statute on other grounds); *Smith*, 507 U.S. at 204 (no clear evidence of congressional intent to apply the Federal Tort Claims Act extraterritorially); *Small v. United States*, 544 U.S. 385, 390 (2005) (“apply[ing] an ordinary assumption about the reach of domestically oriented statutes” in order to “determine Congress’ intent where Congress likely did not consider the matter and where other indicia of intent are in approximate balance”). In order to overcome the presumption, the evidence that Congress intended extraterritorial application of a statute must be “clear” (*Smith*, 507 U.S. at 204).

Section 319F-4(b)(1) of the PHS Act provides that “[i]f the Secretary issues a declaration under 247d-6d(b) of this title, the Secretary shall, after amounts have by law been provided for the [Covered Countermeasure Process] Fund under subsection (a) of this section, provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration” (42 U.S.C. § 247d-6e(b)(1)). Thus, CICP benefits are only available to eligible individuals if their covered injury is caused by the administration or use of a covered countermeasure pursuant to a declaration issued under 42 U.S.C. § 247d-6d(b) (or a good faith belief of such, which is discussed elsewhere in this regulation). Such a declaration must describe, among other things, the “geographic area or areas” for which liability immunity under the Act is in effect “with respect to the administration or use of the [covered] countermeasure” (section 319F-3(b)(2)(D) of the PHS Act (42 U.S.C. § 247d-6d(b)(2)(D)). This description may be a specification that liability immunity applies “without geographic limitation,” and may include, with respect to individuals in any population identified in the declaration, “a specification, as determined appropriate by the Secretary, of

whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration.” *Id.* Further, the Secretary is required to identify populations of individuals for which liability immunity is in effect with respect to the administration or use of the countermeasure, “which may be a specification that such subsection applies without geographic limitation to all individuals” (section 319F-3(b)(2)(C) of the PHS Act (42 U.S.C. § 247d-6d(b)(2)(C)). These population and geographic limitations established in a declaration affect the availability of benefits under the CICP because, as noted above, the Secretary must be persuaded that injured countermeasure recipients used or were administered covered countermeasures in accordance with all of the specifications of a declaration (including any geographic limitations), or a good faith belief of such, in order to award compensation to any requester (*see* § 110.3(n); *see also* 42 U.S.C. § 247d-6e(a), (b)(1) (2005)). Although the PREP Act grants the Secretary authority to specify geographical limitations in her declarations, there is no clear evidence that Congress intended the PREP Act’s compensation provisions to apply extraterritorially. In particular, although the PREP Act directs the Secretary to establish in each declaration the “geographic area or areas” in which liability immunity will apply, in the Secretary’s view this language does not itself supply the clear evidence that Congress intended the compensation provisions to apply extraterritorially (*cf. Aramco*, 499 U.S. at 251 (declining to “deduce[]” extraterritorial application “by inference from boilerplate language”); *Foley Bros., Inc. v. Filardo*, 336 U.S. 281, 287 (1949) (declining to read the phrase “every contract,” “by virtue of the broadness of the language,” to “of necessity” “include contracts for work to be performed in foreign countries”)). In the absence of any other indication that Congress intended the term “geographic area or areas” to include areas beyond the territory or the territorial

jurisdiction of the United States, the Secretary has determined that her discretion to specify the geographic reach of PREP Act declarations does not include the authority to extend those declarations beyond such areas. Thus, when the Secretary specifies that a PREP Act declaration shall have “no geographic limitation,” that does not mean that the declaration may apply, for CICP purposes, outside the territory or the territorial jurisdiction of the United States. Although each declaration is unique and all are subject to amendment through publication in the Federal Register, the PREP Act declarations published to date provide no geographic limitation and generally apply to any populations that use or are administered the countermeasures in accordance with the terms of the declarations.

The PHS Act provides that in order to be entitled to compensation under the CICP, a covered individual must have been administered, or used, a covered countermeasure, section 319F-4(e)(2), 42 U.S.C. § 247d-6e(e)(2), and this regulation’s definition of an injured countermeasure recipient incorporates this requirement. The Secretary has determined that the only way to limit the application of the PREP Act’s compensation provisions to the territory or the territorial jurisdiction of the United States is to limit eligibility to Requests for Benefits relating to covered countermeasures administered or used within the territory of the United States or to places within the territorial jurisdiction of the United States. The Supreme Court has described the territorial jurisdiction of the United States as places over which the United States has sovereignty or some measure of legislative control. *Aramco* 499 US at 248 (citing *Foley Bros*, 336 U.S. at 285). In other words, as long as other eligibility requirements are satisfied (including that the covered countermeasure was administered or used in a covered location), CICP benefits may be paid without regard to whether or not the requester is a citizen or resident of the United States.

The Secretary’s conclusion that the compensation available under the PREP Act does not apply to covered countermeasures administered or used outside of the territory or the territorial jurisdiction of the United States is confirmed by comparison to a similar statutory scheme (*Cf. Aramco*, 499 U.S. at 258). (“Congress’ awareness of the need to make a clear statement that a statute applies overseas is amply demonstrated by the numerous occasions on which it has expressly legislated the extraterritorial application of a statute.”). Congress expressly addressed extraterritorial application of the National Vaccine Injury Compensation Program (VICP), authorized by the National Childhood Vaccine Injury Act of 1986, *et seq.*, 42 U.S.C. § 300aa-10, *et seq.* (the Vaccine Act). The Vaccine Act provides that eligible vaccine recipients must have: “(I) received the vaccine in the United States or in its trust territories; (II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen; or (III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination. . . .” (section 2111(c)(1)(B) of the PHS Act (42 U.S.C. § 300aa-11(c)(1)(B)). While the PREP Act has addressed the issue of territorial limitations somewhat differently, it is apparent that Congress knows how to address extraterritorial administrations of vaccines in the context of a domestic vaccine-injury compensation program, but chose not to insert such a provision in the PREP Act, even though the definition of covered countermeasures under the PREP Act can encompass vaccines (section 319F-3(i)(1) of the PHS Act (42 U.S.C. § 247d-6d(i)(1))). This is notable given that other provisions of the PREP Act follow a similar approach to the corresponding provisions of the

Vaccine Act (*e.g.*, authorizing the Secretary to establish a Table setting forth covered injuries for covered vaccines that creates a rebuttable presumption of causation).

The Secretary acknowledges that a requirement that covered countermeasures be used or administered within the territory or the territorial jurisdiction of the United States in order for compensation under the CICIP to be available, as set forth in § 110.3(f)(2), may lead to disapprovals of CICIP benefits for certain otherwise eligible requesters. For example, individuals may be administered covered countermeasures in clinical trials conducted outside of the United States. In certain circumstances, American citizens may use or be administered covered countermeasures outside of the territory or the territorial jurisdiction of the United States. In addition, given the PREP Act's requirement that covered countermeasures be licensed or approved in specified manners by the FDA, as defined in sections 319F-3(i)(1) and 319F-4(e)(1) of the PHS Act, certain countermeasures administered or used abroad might not meet this PREP Act requirement (42 U.S.C. §§ 247d-6d(i)(1), 247d-6e(e)(1)).

The Secretary has considered the impact of her conclusion that CICIP benefits are not available for individuals who use or are administered covered countermeasures outside of the territory or the territorial jurisdiction of the United States upon individuals who used or were administered covered countermeasures at American embassies or military bases abroad. As noted earlier, the Supreme Court held that the "territorial jurisdiction" of the United States includes "places over which the United States has sovereignty or has some measure of legislative control" (*Aramco* 499 U.S. at 248 (citing *Foley Bros.*, 336 U.S. at 285)). Although the treatment of American embassies and military bases abroad by courts considering the issue of territorial jurisdiction is complex, the Supreme Court has concluded that the territorial jurisdiction of the United States extends beyond the borders of the United States. In a case involving Federal *habeas* petitions

filed by detainees at the Guantanamo Bay Naval Base, the Supreme Court held that the presumption against extraterritoriality “certainly has no application to the operation of the habeas statute with respect to persons detained within ‘the territorial jurisdiction’ of the United States” (*Rasul v. Bush*, 542 U.S. 466, 480 (2004) (citing *Foley Bros.*, 336 U.S. at 285)). The Supreme Court found that the Guantanamo Bay Naval Base fell within the territorial jurisdiction of the United States, noting that by the express terms of its agreements with Cuba, the United States exercises “complete jurisdiction and control” over the Guantanamo Bay Naval Base, and may continue to exercise such control permanently if it so chooses (*Rasul* 542 U.S. at 480-81 (citations omitted)).

In considering a statute defining the special maritime and territorial jurisdiction of the United States (set forth in 18 U.S.C. § 7(3)), the Federal Court of Appeals for the Ninth Circuit held that United States’ territorial jurisdiction need not be exclusive and that American jurisdiction could be concurrent with that of another nation (*U.S. v. Corey*, 232 F.3d 1166, 1178-79 (9th Cir. 2000)). Describing “legislative jurisdiction” as the “jurisdiction to prescribe,” meaning the State’s authority “to make its laws applicable to the activities, relations, or status of persons,” the Court held that such jurisdiction extended to an American Air Force Base in Japan and a private apartment building in the Philippines leased by a United States embassy for its employees, concluding that the United States had concurrent jurisdiction over both (*Id.* at 1177, 1183). This determination was made by referring to the text of the statute, the relevant international agreements, and the practical realities of the situation (*Id.*). The treaties permitted the United States the “power-and the responsibility- to regulate affairs on both territories” (*Id.* at 1181). Considering the same statute, several courts have held that the United States exercises such control over embassies or other Federal establishments that they should be constructively

regarded as United States territory (*Corey*, 232 F.3d at 1178 (citing *U.S. v. Erdos*, 474 F.2d 157, 159 (4th Cir. 1973) (describing the practical usage and dominion test under which the Court shall consider whether the United States enjoys control over an area that the law would constructively regard it as territory of the United States and finding this test satisfied by dominion of the United States over embassy territory in Equatorial Guinea); *U.S. v. Blunt*, 558 F.2d 1245, 1246-47 (6th Cir.1977) (finding a Federal prison in Kentucky to be United States territory even though the United States did not hold title to the property)). *But see U.S. v. Gatlin*, 216 F.3d 207, 211 (2nd Cir. 2000) (interpreting the “special maritime and territorial jurisdiction of the United States” in 18 U.S.C. § 7(3)) not to apply extraterritorially and concluding that a statute prohibiting sexual abuse of a minor while in such jurisdiction did not apply to conduct on a United States military installation abroad); *McKeel v. Islamic Republic of Iran*, 722 F.2d 582, 588 (9th Cir. 1983) (holding that American embassies are not within the territorial jurisdiction of the United States in a case involving the Foreign Sovereign Immunities Act).

On balance, the Secretary expects that most, if not all, United States embassies and military bases abroad constitute places over which the United States has sovereignty or some measure of legislative control for purposes of the PREP Act’s compensation provisions. This determination is informed by the Secretary’s understanding of the PREP Act, as well as her understanding of the degree to which the United States generally exercises sovereignty or some measure of legislative control in such places abroad. In interpreting § 110.3(f)(2), the Secretary will give a presumption, for the purpose of administering the CICP, that American embassies and military bases are places over which the United States has sovereignty or some measure of legislative control. In other words, the Secretary will give a presumption that American embassies and military bases abroad fall within the territorial

jurisdiction of the United States. Under this presumption, the fact that covered countermeasures were used or administered in such places will not preclude otherwise eligible individuals from receiving CICP benefits. This presumption could be rebutted if the Secretary receives evidence supporting a contrary conclusion.

Informed by similar considerations, as well as her understanding of the North Atlantic Treaty Organization Status of Forces Agreement (NATO SOFA), which provides the Sending State with the authority to exercise jurisdiction in certain matters, the Secretary will afford a similar rebuttable presumption for covered countermeasures that are used or administered in NATO installations (subject to the NATO SOFA) in which American servicemen and servicewomen are stationed. Thus, the Secretary will afford a rebuttable presumption that countermeasures used or administered on such NATO installations qualify as the territorial jurisdiction of the United States for purposes of determining CICP eligibility.

Survivors (§ 110.11)

Section 110.11 describes the categories of eligible survivors in the event that the injured countermeasure recipient dies. Survivors may be eligible to receive death benefits under the Program if the Secretary determines that the otherwise eligible injured countermeasure recipient sustained a covered injury and died as a direct result of the injury. Thus, if the Secretary determines that the injured countermeasure recipient died of a cause unrelated to the covered injury, survivors are not eligible to receive death benefits (regardless of the seriousness of the covered injury).

With limited exceptions, the CICP 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. The order of priority for survivors to receive death benefits under the Program is subject to future changes made to 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 (as defined in § 110.3(e)). This definition is based on the definition of “child” within the PSOB. 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, at the time of that individual’s death, is 18 years of age or younger (*i.e.*, has not reached 19th birthday), or between 19 and 22 years of age and a full-time student, or is older than 18 years of age and incapable of self-support because of physical or mental disability. For clarity, § 110.3(e) defines a stepchild, based on the PSOB’s definition of a stepchild, and a posthumous child (a child born after the death of a parent).
- (3) Individuals designated by the deceased person as the beneficiaries under the deceased person’s most recently executed life insurance policy; or
- (4) Surviving parents (of deceased children or adults).

Such survivors, as defined under the PSOB Program, are also eligible survivors under this Program.

The PREP Act, following 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 (have not reached their 18th birthday). This category could include children who also meet the requirements of category 2

above (surviving eligible children). However, it also includes persons who would not qualify as surviving eligible children (for example, a nephew who was supported by the deceased injured countermeasure recipient, but who was not adopted). Persons who satisfy both category 6 and category 2 (surviving eligible children) may be able to choose between death benefits under the standard calculation and death benefits under the alternative calculation.

As discussed below, special criteria apply to the final category of eligible survivors. Under current practices, in the event that a deceased injured countermeasure recipient is survived by a spouse and eligible children, the spouse will receive 50 percent of the death benefit and the children will divide the remaining 50 percent 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 countermeasure recipient is not survived by a spouse or children, the individual designated by the deceased injured countermeasure recipient as the beneficiary under his or her most recently executed life insurance policy receives the death benefit. If there is no life insurance policy or no surviving designated beneficiary under such a policy, the parents, if living, divide the death benefit in equal shares. If none of these categories of survivors exists, the legal guardian of a deceased minor (who was an injured countermeasure recipient) with no living parent will receive the death benefit, if applicable. As explained in § 110.11(b)(5), surviving dependents younger than the age of 18 (category 6 above) have the same priority as surviving eligible children (category 2 above).

Only the legal guardians of persons qualifying both as surviving eligible children (category 2 above) and as dependents younger than the age of 18 (category 6 above) can choose between a proportional death benefit under the standard and the alternative methods of payment for death benefits, described in detail in § 110.82. 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 death benefit calculation. Dependents who are minors and who do not qualify under another category of eligible survivors (under the example given above, a nephew who was supported by the deceased injured countermeasure recipient, but never adopted) are only covered by the alternative method of payment. In the event that survivors are eligible for death benefits under the Program, Program staff will be able to assist families concerning the standard and alternative calculation of death benefits once a determination is made concerning eligibility.

Serious Physical Injuries

As set forth in § 110.20(b), and pursuant to section 319F-4(e)(3) of the PHS Act, only serious physical injuries or deaths are covered by the Program (42 U.S.C. § 247d-6e(e)(3)). The definition of a serious physical injury included in the liability provisions of the PREP Act apply only to those provisions and to lawsuits pursuing claims of willful misconduct. Congress did not mandate that the same definition apply within the CICP. Under the definition pertaining to the liability provisions of the PREP Act, a serious physical injury is defined as an injury that (a) is life threatening; (b) results in permanent impairment of a body function or permanent damage to a body structure; or (c) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure (section 319F-3(i)(10) of the PHS Act (42 U.S.C. § 247d-6d(i)(10))). Under the CICP, § 110.20 clarifies that physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious physical injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of

function or disability (whether or not hospitalization was warranted) will be considered serious physical injuries. Hereafter serious physical injuries will be referred to as serious injuries. This includes instances in which there may be no measurable anatomic or structural change in the affected tissue or organ, but there is an abnormal functional change. For example, many psychiatric conditions are caused by abnormal neurotransmitter levels in key portions of the central nervous system. Thus, it is possible that certain serious psychiatric conditions may qualify as serious physical injuries if the psychiatric conditions are a manifestation of a physical biochemical abnormality in neurotransmitter level or type caused by a covered countermeasure. One way of determining that an abnormal physical change in neurotransmitter level is causing the injury would be a clinical challenge that demonstrates a positive clinical response to a medication that is designed to restore the balance of appropriate neurotransmitters necessary for normal function in an injured countermeasure recipient. However, minor injuries do not meet this definition. For example, covered injuries do not include common and expected skin reactions (such as localized swelling or warmth that is not of sufficient severity to warrant hospitalization and that does not lead to a significant loss of function or disability) or expected minor scarring at the vaccination site (as occurs commonly with smallpox vaccinations).

Unlike under the VICP, the effects of an injury need not last for a certain period of time (or result in inpatient hospitalization or surgical intervention) for it to be considered a serious injury under the CICP. Therefore, some injured countermeasure recipients may be able to show that they sustained a serious injury which resolved within a relatively short time-frame (for example, a person who sustains a serious injury as the direct result of a covered countermeasure which is successfully treated after two weeks of hospitalization).

The Secretary will consider the unique circumstances of each injury claimed and will make determinations on a case-by-case basis as to whether particular injuries can be considered serious injuries.

Injuries Sustained as a Direct Result of a Disease, and not of a Covered Countermeasure

Section 110.20(e) makes clear that an injury sustained as the direct result of a disease (or health condition or threat to health) for which the Secretary recommended the administration or use of a covered countermeasure in a PREP Act declaration is not a covered injury. Thus, if an injury was caused by a disease, and not as a direct result of the administration or use of a covered countermeasure, it cannot qualify as a covered injury. If a covered countermeasure is ineffective in preventing or treating a disease and an individual suffers the disease, an injury resulting from the disease would not be a covered injury because the injury results from the disease and not from the administration or use of the covered countermeasure. Two examples may be illustrative. Under the first example, an individual receives the 2009 H1N1 vaccine and then goes on to develop 2009 H1N1 influenza because the person failed to develop an immune response to the vaccine. Currently, no vaccine achieves 100% efficacy in stimulating a protective immune response in the population. This is sometimes referred to as failure of vaccine efficacy. If a vaccine recipient suffers a serious complication as the result of contracting the circulating 2009 H1N1 virus, and not as the result of the 2009 H1N1 vaccine or another covered countermeasure, such injury will not qualify as a covered injury because it results from the disease itself and would have occurred even if the vaccine had not been administered. Under a second example, a person suffering from serious complications as a result of contracting the 2009 H1N1 virus is put on a ventilator that qualifies as a covered countermeasure under a PREP Act declaration. The ventilator malfunctions and the individual suffers a serious health injury as

a result of the ventilator malfunction. Such an injury may qualify as a covered injury because it would result from the use of a covered countermeasure (a ventilator) and not directly from the underlying 2009 H1N1 disease. In considering whether an injury results from the administration or use of a covered countermeasure, as opposed to the disease itself, the Secretary will evaluate whether the injury directly resulted from a component or a function of the covered countermeasure (in which case, the injury may qualify as a covered injury) as opposed to the disease itself (in which case, the injury cannot qualify as a covered injury even if a covered countermeasure was administered or used, but was ineffective). Some covered countermeasures may contain attenuated live organisms, such as intranasal 2009 H1N1 vaccine or smallpox vaccine. Despite attenuation, serious infections can rarely be caused by these types of countermeasures. A serious injury resulting from this type of infection (as a result of vaccination) in an injured countermeasure recipient could qualify as a covered injury because it would directly result from the administration or use of a covered countermeasure.

With limited exceptions, the PREP Act provides that the CICIP's procedures for determining eligibility, whether eligible persons have sustained covered injuries, whether compensation may be available, and the amount of such compensation shall be the same as those authorized by the SEPPA and implemented in the SVICP. One of these exceptions pertains to individuals who were eligible to apply under the SVICP as a "contact case" based on accidental vaccinia inoculation. The PREP Act makes clear that individuals who contract a disease as a result of contact with a person who used or was administered a covered countermeasure (or other close contacts) may not pursue claims under the CICIP for any resulting injuries (sections 319F-4(b)(4), (e)(2), and (e)(5) of the PHS Act (42 U.S.C. § 247d-6e(b)(4), (e)(2), and (e)(5))). Thus, although it is possible that in some circumstances, individuals may suffer injuries as a result of

diseases contracted after exposure to individuals because of their use or administration of covered countermeasures (for example, a person who contracts vaccinia after close contact with another person who was administered a smallpox vaccine that qualifies as a covered countermeasure), such contacts cannot pursue benefits under the CICP for such injuries.

Contracting a disease in such a manner is extremely rare and will generally only be possible with vaccines containing live viruses.

How to Establish a Covered Injury (§ 110.20)

Covered injuries are defined in § 110.3(g) and are set out in Subpart C of this rule. Covered injuries are defined as serious injuries (or deaths) sustained by injured countermeasure recipients that the Secretary determines are either: (1) an injury meeting the requirements of a Countermeasure Injury Table (Table), discussed below; or (2) an injury that is, in fact, the direct result of the administration or use of a covered countermeasure. The latter requirement includes serious aggravations of pre-existing conditions if such aggravations were caused by a covered countermeasure (*e.g.*, a seizure disorder that is proven, to the satisfaction of the Secretary, to have been made significantly more serious as the direct result of the administration or use of the countermeasure). All requesters (including survivors and executors or administrators of the estate of a deceased countermeasure recipient) must demonstrate that an injured countermeasure recipient sustained a covered injury in order to be eligible for any benefits under the CICP.

Table injuries

Section 110.20(c) discusses Table injuries. As noted above, one way that requesters can demonstrate that they sustained a covered injury is by demonstrating that they sustained an injury listed on a Countermeasure Injury Table (Table) within the time interval set forth on the Table, as set out in Subpart K (§ 110.100 *et seq.*) of this rule. In accordance with the PREP Act

(following the SEPPA), an injured countermeasure recipient shall be presumed to have sustained a covered injury as the direct result of the administration of a covered countermeasure if the requester submits sufficient documentation demonstrating that the injured countermeasure recipient sustained an injury included on a Table, with the onset of the first sign or symptom within the time interval specified on the Table. The injury must also meet the Table's definitions and requirements, which will be described under Subpart K. In such circumstances, the Secretary will presume, solely for purposes of the Program, that the injured countermeasure recipient's injury was caused by the covered countermeasure (absent another cause, as described below). Such a requester need not actually demonstrate that the covered countermeasure caused the underlying injury, only that an injury listed on the Table (and meeting the Table's definition) 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 PREP Act to do so. For this reason, based on her review of the submitted documentation and other relevant evidence, and consistent with the regulations implementing the SVICP, the Secretary may determine that an injury meeting the Table requirements was actually caused by other factors and was not caused by the covered countermeasure (*e.g.*, if the Secretary determined that the medical records demonstrated that an individual's injury of encephalopathy, a type of brain injury, was caused by a car accident that occurred after a covered countermeasure was used, and neither the encephalopathy nor the car accident was caused by the covered countermeasure itself). In these circumstances, which we expect to occur rarely, the Secretary could rebut a Table presumption of causation and decide that the requester not be afforded the presumption of a Table injury.

The Secretary is authorized under the PREP Act to issue Table(s) for each covered countermeasure identified in a PREP Act declaration. According to the PREP Act, the Secretary may only identify such covered injuries, for purposes of inclusion on a Table, in circumstances where the Secretary determines, based on “compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury” (section 319F-4(b)(5)(A) of the PHS Act (42 U.S.C. § 247d-6e(b)(5)(A)). The Secretary plans on reviewing the available scientific evidence concerning covered countermeasures identified in PREP Act declarations and to issue such Tables, when appropriate, through rulemaking. In an effort to administratively implement the Program as soon as possible, the Secretary is not including such Tables within this rulemaking, but should such Tables be issued in the future, she will do so as amendments to this rule.

Non-Table injuries

Section 110.20(c) discusses non-Table injuries. Certain requesters who are unable to demonstrate a Table injury may still be able to show that they sustained a covered injury. Such requesters may include those who believe that an injury included on a Table was sustained, but who did not meet all the Table requirements (*e.g.*, the onset of the injury did not occur within the required time interval included on the Table) or those whose injuries are not included on a Table. To establish a covered injury in such circumstances, the Secretary must determine that the injury sustained was the direct result of the administration or use of a covered countermeasure. Under the PREP Act, the Secretary may only make such determinations based on compelling, reliable, valid, medical and scientific evidence (section 319F-4(b)(4) of the PHS Act (42 U.S.C. § 247d-6e(b)(4)). As described in § 110.20(d), requesters with such claims may need to submit sufficient relevant medical documentation or scientific evidence (such as studies published in

peer-reviewed medical literature). In evaluating such claims, the Secretary will take into consideration relevant medical and scientific evidence, including relevant medical records. As provided under the PREP Act, this determination is not reviewable by any court (section 319F-4(b)(5)(C) of the PHS Act (42 U.S.C. § 247d-6e(b)(5)(C)). Temporal association between administration or use of the covered countermeasure and onset of the injury (*i.e.*, the injury occurs a certain time after the administration or use) is not sufficient, by itself, to prove that an injury is the direct result of a covered countermeasure.

Benefits Available to Different Categories of Requesters (§ 110.30)

An eligible requester who is an injured countermeasure recipient may be eligible to receive medical benefits, benefits for lost employment income, or both, as long as he or she provides the appropriate documentation. For example, such requesters must submit documentation showing that they have incurred unreimbursable, reasonable, and necessary medical expenses as a result of a covered injury or its health complications to receive medical benefits, and documentation showing that they lost employment income as a result of a covered injury or its health complications for a specified period in order to receive benefits for lost employment income. Such documentation requirements are discussed later in this rule.

An eligible requester who is a survivor of an otherwise eligible deceased injured countermeasure recipient ~~may be able to receive~~ can only receive a death benefit as a survivor, and no other benefits. Such death benefits are only available if the survivors demonstrate to the satisfaction of the Secretary that the death was caused by the covered injury or its health complications.

The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits, benefits for lost employment income, or both if such benefits

were accrued, but were not paid in full, during the deceased person's lifetime. Such benefits may be available regardless of the cause of death. 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 injured countermeasure recipient might have earned if he or she had not died. In addition, the estate would not be eligible for death benefits, as those benefits are only available to survivors.

Medical Benefits - Summary and Calculation (§ 110.31 and § 110.80)

Medical benefits that may be available under the Program are described in § 110.31. Under the PREP Act, the medical benefits that shall be provided have the same elements and shall be in the same amount as those prescribed by section 264 of the PHS Act (the relevant provision of the SEPPA) (42 U.S.C. § 239c). 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 for the diagnosis, treatment, or prevention of the injury's direct health complications. Past, current, and expected future medical services and items may be included in medical benefits. The Secretary is authorized to pay for medical services or items in an effort to cure, counteract, or minimize the effects of any covered injury (or its health complications), or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of benefits to an injured countermeasure recipient. As an example, the CICP may purchase a health insurance policy for an injured countermeasure recipient, which would have the benefit of providing care to the injured countermeasure recipient over the course of years or a lifetime and the attendant benefit of being an efficient use of Federally-appropriated

funds (as compared with direct payments for the services and items covered by the purchased health insurance policy).

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 healthcare provider. In considering benefits for future medical services and items, the Secretary may consider statements by healthcare providers 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. However, the Secretary is not bound by such statements. In addition, the Secretary may consider whether the services and items are within the standard of care for the injured countermeasure recipient's medical condition.

As set forth in § 110.31(b), for a requester to receive medical benefits for a health complication of a covered injury, the health complication must have resulted from the covered injury or its treatment and must not be more likely due to other factors or conditions. Examples of health complications include ill effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a diagnostic test used in connection with a covered injury, or a complication of a surgical procedure used to treat the covered injury.

As explained in § 110.31(d), if an injured countermeasure recipient dies before filing with, or being fully paid by, the Program, the deceased person's estate may be eligible for benefits for the cost of medical services and/or items accrued during his or her lifetime as a result of the covered injury or its health complications provided such payments and expenses were not paid in full by a third party during the deceased injured countermeasure recipient's lifetime.

Because such payments are for medical expenses accrued as a result of a covered injury while the injured countermeasure recipient was alive, the cause of death does not have to be related to the covered injury for these medical benefits to be paid to the estate.

The calculation of medical benefits is described in § 110.80. There are no caps on medical benefits. However, the Secretary may limit the payment of such benefits to the amounts (costs) she considers reasonable for those services and items that she 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 payer, 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 payers that may have an obligation to pay for or provide medical benefits. Because the Program is a secondary payer, requesters are required to make good faith efforts to pursue medical benefits from their primary payers. For example, the Program will generally not pay for medical benefits that are paid or payable by the injured countermeasure recipient's medical insurance. As explained in § 110.31(c), requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. Further, § 110.2(b) explains that the benefits available under the CACP usually will only be paid after the requester has in good faith attempted to obtain all other available coverage from third-party payers with an obligation to pay for or provide such benefits. Thus, the Secretary has the discretion not to pay medical benefits if a requester has not made such good faith attempts.

When the Secretary has determined that the requester is eligible for medical benefits and the documentation needed to compute the amount is available, she will do the following, consistent with the calculations described in § 110.80:

- (1) Determine which medical expenses that have been submitted are reasonable and necessary to diagnose or treat a covered injury or to diagnose, treat, or prevent 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 the computation the total amount paid, or payable, by all other third-party payers.

This will be the basis for the Program's payment. For example: an eligible injured countermeasure recipient 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 this preamble, the Secretary may make a payment of medical benefits and later pursue such a payment from a third-party payer with an obligation to pay for or provide the medical services or items.

Lost Employment Income - Summary and Calculation (§ 110.32 and § 110.81)

Lost employment income benefits that may be available under the Program appear in § 110.32. Under the PREP Act, compensation for lost employment income under this Program shall have the same elements and shall be in the same amount as prescribed by section 265 of the PHS Act (the relevant provision of the SEPPA) (42 U.S.C. § 239d). The CICP will provide benefits for lost employment income (secondary to other benefits that may be available to the requester), subject to limitations described in § 110.81(c), 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), and supported by the degree of disability or injury, medical and employment records.

These benefits are a percentage of the employment income lost at the time of injury, due to the covered injury or its health complications, and are based on the number of eligible work days for which such income was lost. Employment income means the injured person's gross employment income at the time of injury. 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 work day 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 may be considered one total day of lost wages. As described in § 110.32(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 where the injured person reimburses the employer for the wages paid and the employer restores the paid leave taken so it is available for future use, thus putting the injured countermeasure recipient back in the same position as if he or she had not used paid leave on the lost work day. The Secretary has the discretion to consider the reasonableness of the number of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation, as well as the severity of the covered injury as demonstrated by the medical records, and to consider alternative work schedules in determining the number of work days lost.

Under the PREP Act, following 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 countermeasure recipient lost employment income for ten 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 (or fewer) of employment income as a result of a covered injury, he or she will not be eligible for any benefits for lost employment income. An injured countermeasure recipient 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 five days.

The calculation of benefits for lost employment income is described in § 110.81. The annual cap on benefits for lost employment income 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, to document his or her employment income. Pursuant to the PREP Act (incorporating the SEPPA), the lost employment income benefit terminates once the injured countermeasure recipient reaches the age of 65. Benefits that represent future lost employment income will be adjusted to account for inflation. It is important to note that future lost employment income will be calculated based on an individual's gross 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 the lost employment income 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 \$311,810, but subject to change each fiscal year). 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, an injured countermeasure recipient determined by the Secretary to have a permanent and total disability may be eligible to receive up to \$50,000 a year until he or she reaches the age of 65, without regard to the lifetime cap.

As is the case for medical benefits, if an injured countermeasure recipient dies before filing for, or being fully paid, benefits for lost employment income incurred during his or her lifetime as a result of a covered injury or its health complications, the executor or administrator 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. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure recipient, of death benefits under § 110.82.

Once the Secretary has determined that she has all the information necessary to compute lost employment income, the calculation will be made as follows, as set out in § 110.81:

(1) The Secretary will make a calculation concerning the number of lost work days that are reasonable based on the degree of injury or disability.

(A) If the injured countermeasure recipient lost five days or fewer of employment income, then no benefits for lost employment income will be paid.

(B) If the injured countermeasure recipient lost six to nine days of employment income, then the Secretary will subtract five days from the number of lost work days for which lost employment income can be paid.

(C) If the injured countermeasure recipient lost ten or more days of employment income, then every lost work day will be counted in calculating the lost employment income benefit.

(2) The Secretary will multiply the injured countermeasure recipient'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.

(3) The Secretary will compute 75 percent of the lost employment income if the injured countermeasure recipient had one or more dependents (at the time of the covered injury) or 66 2/3 percent 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.

(4) The amount of payment will be reduced by any benefit that the requester is entitled to receive from a third-party payer (*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 payer 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 employee or the State if its program determines that such a benefit is due the requester).

(5) The payments made will be subject to an annual cap of \$50,000.

(6) 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.

Death Benefits - Summary and Calculation (§ 110.11, § 110.33, and § 110.82)

Certain survivors of injured countermeasure recipients who died as a direct result of a covered injury or its health complications may be eligible for death benefits, as set out in §

110.11 (eligible survivors and their priority to receive death benefits), § 110.33 (general description of death benefits) and § 110.82 (calculation of death benefits).

Under the PREP Act, compensation for death benefits has the same elements and shall be in the same amount as prescribed by section 266 of the PHS Act (the relevant section of the SEPPA) (42 U.S.C. § 239e). Thus, in accordance with the PREP Act (incorporating SEPPA), death benefits under the CICP may be available under one of two different calculations: the “standard calculation” or the “alternative calculation.” The “standard calculation” is a lump-sum payment to eligible survivors and is described in § 110.82(b). 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 § 110.82(c). This method is based upon the deceased person’s employment income at the time of the covered injury.

Filing a Request Package (§ 110.40-§ 102.41)

A Countermeasures Injury Compensation Program Request for Benefits Form (hereinafter "Request Form") will be available from the Program. In order for a requester to have his or her Request for Benefits reviewed by the Program, the requester must submit, at a minimum, a completed Request Form (or a Letter of Intent to file a Request Form, described below) 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 all supporting documentation (the Request Package) to the address listed in § 110.41. To avoid any delays in implementing the

Program, the Program will not accept Request Forms or Request Packages electronically at this time. However, the Program will publish a notice in the future if electronic filing becomes available. Once the Program assigns a case number to a requester, all related correspondence should reference the assigned case number.

Filing Deadlines (§ 110.42)

Under the PREP Act, the filing deadlines that applied under SEPPA are mandatory with respect to Request Forms filed with this Program. For that reason, injured countermeasure recipients have one year from the date of the administration or use of a covered countermeasure to submit a Request Form (or Letter of Intent to file a Request Form, as described in § 110.42(b)). For covered countermeasures used or administered over a period of time (for example, antibiotics taken daily for seven days), the filing deadline is one year from the latest administration or use associated with the covered injury. For vaccines administered in more than one dose on different dates (for example, 2009 H1N1 vaccines given in two doses one month apart), the filing deadline is one year from the date of the vaccine administration associated with the injury. Because the PREP Act, incorporating SEPPA, refers to requests based on the administration or use of the countermeasure, the filing deadline that applies to Request Forms filed by injured countermeasure recipients is the same filing deadline that applies to Request Forms filed by the survivors or the representatives of the estates of deceased injured countermeasure recipients. This one-year filing deadline is absolute, regardless of when the first symptoms of the injury occur or when individuals suspect that the injury may have been caused by a covered countermeasure. Likewise, the one-year filing deadline applies to injuries sustained by a child described in section 110.3(n)(3) (a child under certain circumstances whose covered injuries were the direct result of a covered countermeasure's administration to, or use by, the

mother of the child when she was pregnant with that child). The filing deadline for a Request for Benefits to compensate a child qualifying as an injured countermeasure recipient under section 110.3(n)(3) is one year from the date of administration or use of the covered countermeasure during the mother's pregnancy. Pursuant to statute, the date of the child's birth, the date the injury is discovered, or the date the injury is diagnosed is not the basis of determining the filing deadline.

This one-year filing deadline does not apply to *amendments* to previously filed Request Forms. As explained later in the discussion of § 110.46, if an injured countermeasure recipient filed a Request Form within the filing deadline and later dies, his or her survivor(s) (or the representative of his or her estate) may later amend the original Request Package outside of the filing deadline (because the original Request Form was timely filed).

As described in § 110.42(b), requesters may meet the Program's filing deadline by filing a Letter of Intent to file a Request Form within the governing filing deadline. This mechanism is available to ensure that persons with potential claims will have a means of meeting the Program's filing deadline even if all of the pertinent documents (*e.g.*, administrative regulation, Request Forms and Instructions) are not yet available. The Program previously notified the public of the ability to file Letters of Intent even before the Program's regulations are published and the Program's forms and instructions are available. The Program has made this information available on HRSA's web site. Thus, if a requester files a Letter of Intent to file within one year of administration or use of the covered countermeasure that is thought to have caused the injury, then the requester has met the filing deadline. The Program has already received several such letters. All requesters who file a Letter of Intent should file a Request Form as soon as possible after the Request Form becomes available.

As set forth in § 110.42(d), Request Forms (or Letters of Intent) not filed within the governing filing deadline will not be processed, and the requester will not be eligible for any Program benefits.

Section 110.42(e) also provides for “constructive receipt” of Request Forms, at the Secretary’s discretion. When a requester files a legal action with the Federal Government (*e.g.*, a claim filed pursuant to the Federal Tort Claims Act (FTCA) or a petition for compensation with the VICP) that concerns an alleged injury resulting from the administration or use of a covered countermeasure, then the Secretary may consider the filing of such a legal action (whether an administrative action or a lawsuit) to be “constructive receipt” of a Request Form or Letter of Intent filed under the CACP, for the purposes of determining the filing date. Given the one-year statute of limitations for this Program and the fact that not all potentially eligible persons may be aware of the Program, the Department may offer such constructive receipt in appropriate circumstances to ensure that claims or lawsuits filed concerning injuries or deaths allegedly resulting from CACP covered countermeasures will be considered by the CACP. Thus, if an individual files a VICP claim concerning an injury allegedly sustained as the result of a covered countermeasure and such legal action is filed in the United States Court of Federal Claims within one year of its administration or use, the Secretary has the discretion to decide that the claim was “constructively received” by the Government on the date that such action is filed in court. Despite the Secretary’s ability to consider certain submissions as timely filings for the Program relying on such “constructive receipt,” there is no guarantee that the Secretary will follow this approach in particular cases, and potential requesters must file Request Forms (or Letters of Intent) within the appropriate Program filing deadline in order to be assured of timely filing with the Program.

Section 110.42(f) describes an additional filing deadline available to certain requesters with respect to injuries added to Covered Countermeasures Injury Tables. Through this regulation, the Secretary is reserving Subpart K of this part for Covered Countermeasures Injury Tables, described above. In order to publish this regulation as soon as possible, the Secretary will publish such Tables separately. However, because those Tables will later be included in this regulation and this part, any initial publications of such Tables or subsequent modifications to such Tables will be considered amendments to this regulation. As described in § 110.42(e), in the event that the Secretary issues a new Covered Countermeasure Injury Table, or amends a previously published Table, requesters will have an extended filing deadline based on the effective date of the Table amendment. However, this extended filing deadline will only apply to requesters if the Table amendment enables a person who could not establish a Table injury before the amendment to establish such an injury. As a hypothetical example, if the Secretary amends this regulation in the future by adding a Table for the 2009 H1N1 vaccine and the Secretary includes an associated injury of anaphylaxis, any person who meets the Table requirements for an injury of anaphylaxis after receiving the 2009 H1N1 vaccine (*i.e.*, suffered the injury of anaphylaxis according to any definitions included on the Table, and suffered the onset of the injury within the time frame listed on the Table after the vaccine administration) would have one year from the effective date of the Table change adding the injury of anaphylaxis to file a Request Form. Such an individual will be afforded this alternative filing deadline because this Table change would enable this potential requester to establish a Table injury. For such persons, this alternative filing deadline applies regardless of whether the requesters previously filed a Request Form with the Program. The filing deadline provided under § 110.42(f) is an additional and alternative filing period to the one afforded to all potential

requesters under § 110.42(a). Therefore, persons who would be eligible to use the filing deadline described in § 110.42(f) could rely on the deadline provided under § 110.42(a) or § 110.42(f). Depending on the factual circumstances, it is possible that one or the other deadline could provide a potential requester with a longer period in which to file a Request Form. This additional filing deadline is authorized by the PREP Act's incorporation of SEPPA's filing deadlines for Table amendments. We expect that the filing deadline described in § 110.42(f) may make benefits available to individuals who would otherwise be time-barred with respect to injuries for which new scientific evidence becomes available linking a particular covered countermeasure with a particular injury.

It is important to note that the additional filing deadline described in § 110.42(f) is only available to persons who are provided with the presumption of causation of a Table injury by virtue of changes made to a Table. Persons who sustained other injuries or who do not meet all of the requirements for such a Table injury (for example, the definition included on the Table, and the time-frame for onset included on the Table) will not be afforded an additional one year filing deadline based on the effective date of the Table change. Because the Table change would not enable such individuals to establish a Table injury, they would be subject to the standard filing deadline described in § 110.42(a).

Deadlines for Submitting Documentation (§ 110.43)

As described above, a requester will meet the filing deadline requirement by submitting a completed and signed Request Form (or Letter of Intent) within the filing deadline set forth in § 110.42, with documentation to follow at a later date. Although the Secretary will accept documentation required to make eligibility determinations (*i.e.*, documentation described in § 110.50 and §§ 110.51, 110.52, and 110.53 depending upon the nature of the Request) at the time

the Request Form is filed, requesters need not submit such documentation at that time. Submitting eligibility documentation as soon as possible will enable the Secretary to make a prompt eligibility determination. The documentation necessary to make benefits determinations (*i.e.*, documentation described in §§ 110.60, 110.61, 110.62, and 110.63, depending on the type of benefits sought) need not be filed until a requester has been notified by the Secretary that the requester is eligible for Program benefits. However, the Secretary will accept such documentation at an earlier date.

After filing a Request Form (or Letter of Intent) within the filing deadline, a requester must update the Request Package to reflect new information as it becomes available. For example, requesters have an obligation to arrange with their healthcare providers to submit copies of medical records as they are generated.

Legal or Personal Representatives of Requesters (§ 110.44)

Requesters do not need to retain the services of lawyers to pursue benefits under this Program. However, as provided in § 110.44(a), requesters may have a legal or personal representative (*e.g.*, lawyer, guardian, family member, or friend) submit the Request Form (or Letter of Intent) and/or Request Package on their behalf. In certain circumstances, described below, requesters may be required to have a legal or personal representative file on their behalf. All representatives filing on behalf of requesters will be bound by the obligations and documentation requirements that apply to 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 those records on behalf of the requester. If a requester has a legal or personal representative, the Program will generally direct all communications to the representative unless the Program is advised that the representation has stopped. However, as described in §

110.40(a), the Secretary reserves the right to contact the requester directly if necessary (*e.g.*, in circumstances in which the Secretary is unable to contact the representative). The Secretary also reserves the right to contact requesters at a later date to conduct a follow-up survey to help determine improvements in the ability of the Program to meet the needs of requesters.

As described in § 110.44(b), a legally competent requester may use a representative to submit a Request Package on his or her behalf. In such circumstances, the requester must indicate 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 adults who do not have legal capacity to receive payments (*i.e.*, adults determined to be legally incompetent by a court having jurisdiction) are required to have the assistance of a representative (who does not need to be a lawyer). Representatives of requesters who are minors (excepting emancipated minors), or adults determined by a court not to have legal capacity to receive payments, are required to submit specific documentation, in addition to the documentation generally required of requesters, which is described in § 100.63.

As explained above, although legal representation is permitted, it is not needed for filing for Program benefits. As described in § 110.44(d), the Program will not be responsible for the payment or reimbursement of any fees for the services of legal or personal representatives or for any associated costs. The authorizing statute does not permit the Program to pay any attorney's fees or related costs.

Multiple Survivors (§ 110.45)

If there are multiple survivors, then each survivor may submit Request Forms separately or the group of survivors may submit one Request Form together. Multiple survivors are not required to file separate supporting documentation; rather, they may submit one complete set of

supporting documentation on behalf of all survivors.

Amendments to Request Packages (§ 110.46)

The filing of amendments to previously filed Request Packages is discussed in § 110.46. As explained in § 110.46(a), all requesters may amend their documentation concerning eligibility until the Secretary makes an eligibility determination. After that time, the Secretary will not accept additional documentation concerning eligibility (except amendments filed by survivors or the estates of deceased countermeasure recipients, discussed below).

After the Secretary makes a benefits determination (*e.g.*, determines that no benefits may be awarded because all eligible benefits have been paid by other third party payers, or determines that a requester is entitled to benefits and sets the amount of the award), the determination is final and the Secretary will not accept new benefits documentation regarding that covered injury (except amendments filed by survivors or the estates of deceased countermeasure recipients, discussed below). The Secretary believes that benefits determinations must have finality. The Secretary will do her best to assess the appropriate level of benefits based on the information before her at the time of the benefits determination. In certain circumstances, such determinations may be based on the Secretary's assessment of the likely future needs of a requester. For example, a medical benefits award will be based, in part, on the Secretary's best judgment as to the anticipated future course of an injured countermeasure recipient's illness. Because reopening such benefits decisions would create an unreasonable administrative burden and would prevent finality, the Secretary will not consider new evidence concerning the appropriate level or type of benefits after the benefits determination has been made. If another approach were pursued, the Secretary could be in the position of revisiting benefits every time a requester's medical condition or insurance coverage altered, even slightly. The Program is not in

a position to constantly re-evaluate such determinations.

Section 110.46(b) addresses amendments filed by requesters who are survivors. If an injured countermeasure recipient filed a Request Package, but later dies, his or her survivors may amend the Request Package by filing a new Request Form. A survivor filing such an amended request will only be entitled to benefits under the Program if the original Request Form (filed by or on behalf of the injured countermeasure recipient, his or her estate, or other survivors) was filed within the applicable one year 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 need not resubmit such documentation. If the injured countermeasure recipient (or his or her estate) never filed a Request Package, a Request Form filed by a survivor would be considered the beginning of a new Request Package and not an amendment to a previously filed Request Package. As set forth in § 110.46(b), survivors must file an amendment to a Request Package if there is a change in the eligible survivors (for example, the spouse of an injured countermeasure recipient dies).

Section 110.46(c) addresses amendments filed by the executor or administrator of the estate of a deceased injured countermeasure recipient. If an injured countermeasure recipient filed a Request Package, but later dies before all benefits are paid by the Program, the executor or administrator of his or her estate may amend the Request Package by filing a new Request Form. The estate will only be entitled to receive benefits under the Program if the original Request Form (previously filed by or on behalf of the injured countermeasure recipient or his or her survivor(s)) was filed within the applicable one-year 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 executor or administrator of the estate need not

resubmit such documentation. If the injured countermeasure recipient (or his or her survivor(s)) never filed a Request Package, a Request Form filed by the executor or administrator of his or her estate would be considered the beginning of a new Request Package and not an amendment to a previously filed Request Package.

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 Required to Be Deemed Eligible (§ 110.50 - § 110.54)

Requesters or their representatives must submit appropriate documentation sufficient to enable the Secretary to determine whether requesters are eligible for Program benefits. The documentation required will vary somewhat depending on whether the requester is filing as an injured countermeasure recipient, survivor, or estate (through the executor or administrator).

Medical Records Necessary to Determine Whether a Covered Injury Was Sustained (§110.50)

The phrase “medical records” is defined in § 110.3(p), which provides that “medical records” for purposes of this part means “documentation associated with primary care, hospital in-patient and out-patient care, speciality consultations, and diagnostic testing and results.”

Because all Request Packages filed with the Program, including those filed by survivors or executors or administrators of the estates of deceased persons, must relate back to an injured countermeasure recipient who sustained a covered injury, all requesters must submit medical records sufficient to demonstrate to the Secretary that a covered injury was sustained by the injured countermeasure recipient. Section 110.50(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 if an injury appearing in a Table (and meeting the requirements of a Table) was sustained or if an

injury was otherwise sustained as the direct result of the administration or use of a covered countermeasure. The Program will consider copies of medical records to be the same as the original records. Section 110.50 sets forth all of the medical records necessary for the Secretary to determine whether a covered injury was sustained.

As a general matter, the Secretary expects to receive medical records directly from healthcare providers. The Secretary requires that requesters sign an Authorization for Use or Disclosure of Health Information Form (Authorization for Health Information Form), available from the Program, for each applicable healthcare provider authorizing the release of the requested medical records directly to the Program and send copies of each of these Authorization for Health Information Forms to the Program. Section 110.50(b) explains that requesters may submit any additional medical documentation that they believe supports their Request Packages. The Program will not expect such documentation. The medical records described in § 110.50(a) generally will be sufficient for the Program to make a covered injury determination. As an example of the type of documentation described in § 110.50(a), a requester may submit scientific evidence such as a scientific research article in order to demonstrate that an injury was directly caused by the administration or use of a covered countermeasure. In making covered injury determinations, the Secretary may consider the scientific evidence available (*e.g.*, published articles concerning a relationship between the countermeasure and an injury) and consult with qualified medical experts.

Section 110.50(c) addresses circumstances in which certain medical records are unavailable to a requester (*e.g.*, a medical office has closed, records have been destroyed due to a natural disaster, a requester is unable to afford the costs charged by a provider to copy and release medical records). In these cases, the requester must provide a statement describing the

reasons for the records' unavailability and the reasonable efforts the requester has made to provide them. The Secretary may, at her discretion, accept such a statement from the requester instead of the required medical records, if the circumstances so warrant. In addition, the Secretary may, at her discretion, obtain the records directly from healthcare providers on the requester's behalf.

As described in § 110.50(d), the Secretary may determine that particular records described in § 110.50(a) are not necessary for particular requesters (for example, if certain medical records provide the same information as other records that are submitted) or that additional medical records may be required in order to make a covered injury determination. For example, the Secretary generally requires all medical records for one year prior to the administration or use of a covered countermeasure as necessary to indicate the injured countermeasure recipient's pre-existing medical history. Based on her review of such documents, however, the Secretary may require additional information concerning a condition that was pre-existing prior to the injured countermeasure recipient's administration or use of a covered countermeasure to determine the most likely cause of the covered injury. Also, depending on the circumstances of the administration or use of the covered countermeasure and the specifications of the relevant PREP Act declaration, the Secretary may need additional information concerning the circumstances of the administration or use of the covered countermeasure to determine whether the specifications of the declaration were satisfied (or that a good faith belief of such existed). The Secretary will notify requesters in such circumstances.

If an injured countermeasure recipient 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 § 110.52(c), the medical

records reviewed for this purpose may be the same as those submitted for the covered injury determination.

Documentation an Injured Countermeasure Recipient Must Submit for the Secretary to Make a Determination of Eligibility for Program Benefits (§ 110.51)

Section 110.51 sets forth all of the documentation an injured countermeasure recipient must submit in order for an eligibility determination to be made. First, the requester (or his or her representative) must submit a Request Form. Second, requesters must submit records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure (*e.g.*, medical records, vaccination records, records from an employer or public health authority). Third, a requester must submit the medical records described in § 110.50 sufficient to show that the injured countermeasure recipient sustained a covered injury. Fourth, a requester should submit a copy of each signed Authorization for Health Information Form for each healthcare provider authorizing providers to release medical records directly to the Program. As described in § 110.51(b), the Secretary has the discretion to determine that a requester need not submit a copy of such signed Authorization for Health Information Form with respect to each healthcare provider in all circumstances. Finally, as described in § 110.51(b), a requester may be required to submit additional documentation as required by the Secretary. For example, as a general matter, the information provided on the Request Form, together with other documentation submitted with respect to other requirements, will be sufficient for the Secretary to make a determination as to whether the injured countermeasure recipient was administered or used a covered countermeasure in accordance with all of the terms of a Secretarial declaration (including administration or use during the effective period of the declaration) or in a good faith belief that the administration or use met all of the terms of a declaration. However, in certain

circumstances, the Secretary may require requesters to submit additional documentation in order to make an eligibility determination. In appropriate circumstances, the Secretary may determine that all of the records described in § 110.51 will not be required for a particular injured countermeasure recipient. In such circumstances, the Secretary will notify the requester of such.

Documentation a Survivor Must Submit for the Secretary to Make a Determination of Eligibility for Death Benefits (§ 110.52)

Section 110.52 describes the documentation that a survivor must submit for an eligibility determination to be made with respect to survivor death benefits. With the exception of a Request Form, discussed below, there is no need to duplicate documentation already submitted (by an injured countermeasure recipient during his or her lifetime, by the executor or administrator of his or her estate after death, or by another survivor). With respect to all requests for death benefits (payable only to survivors), at least one survivor must file a Request Form. This is true even if the injured countermeasure recipient already submitted a Request Form and the survivor(s) are amending the previously filed Request Package. Section 110.52 makes clear that all of the documentation required for injured countermeasure recipients must be filed for an eligibility determination to be made with respect to death benefits. Additional documentation is also required (*e.g.*, a death certificate for the injured countermeasure recipient, medical records demonstrating that the death was the direct result of a covered injury, documentation showing that the requester is an eligible survivor). As provided in § 110.52(a)(2), the Secretary has the discretion to accept other documentation that the injured countermeasure recipient is deceased if the death certificate is unavailable and the Secretary is satisfied with a letter submitted by the requester concerning the reasons for the unavailability of the certificate. The Secretary expects that this will be a rare occurrence. In addition, in the place provided on the Request Form, a

survivor filing a Request Form must verify that there are no other eligible survivors or that other eligible survivors exist (together with information about such survivors). As noted above, § 110.11 describes eligible survivors for purposes of death benefits and the priorities of survivorship.

Documentation the Executor or Administrator of the Estate of a Deceased Injured Countermeasure Recipient Must Submit for the Secretary to Make a Determination of Eligibility for Benefits to the Estate (§ 110.53)

The executor or administrator of the estate of a deceased injured countermeasure recipient, seeking benefits under the Program on behalf of the estate, must submit a completed and signed Request Form. This is true even if the injured countermeasure recipient or a survivor already submitted a Request Form and the executor or administrator of the estate is amending the previously filed Request Package. In addition, a death certificate for the injured countermeasure recipient is required. As provided in § 110.53(b), the Secretary has the discretion to accept other documentation showing that the injured countermeasure recipient is deceased if the death certificate is unavailable and the Secretary is satisfied with a letter submitted by the executor or administrator concerning the reasons for the unavailability of the certificate. The Secretary expects that this will be a rare occurrence. Although the estate may receive benefits regardless of whether or not the death resulted from a covered injury, the Secretary may require documentation concerning the death in cases in which eligibility has not yet been determined. For example, the Secretary may require such documentation to help determine whether an injury was caused by the administration or use of a covered countermeasure, as opposed to an underlying health condition that might be apparent at death. No death benefits are awarded to the estate. Finally, documentation showing that the individual is the executor or administrator of

the deceased injured countermeasure recipient's estate (*e.g.*, a court order or letters of administration) is required.

Documentation Required for the Secretary to Determine Program Benefits (§ 110.60 -§ 110.63)

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 secondary to benefits received or receivable from third-party payers, it may be possible that certain requesters who are deemed eligible will not receive benefits from the Program. Sections 110.60-110.63 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 § 110.43(b) and is designed to ease the documentary burden on requesters who do not know whether or not they will be deemed eligible.

In order to calculate the amount of each type of benefit available, the Program requires requesters to provide documentation of every third-party payer 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 payers with respect to each type of benefit available under the Program is described in §§ 110.60, 110.61, and 110.62. As set forth in § 110.60(a)(3), a requester may need to give consent for the Program to communicate directly with third-party payers.

Requesters seeking medical benefits must also submit documentation concerning the

amount paid or expected to be paid by such third-party payers for the medical services or items for which payment is being sought under the Program. Third-party payers of medical benefits include, but are not limited to, medical insurance, Medicaid, Medicare, and any other source of medical reimbursement. An example of the documentation necessary to satisfy this requirement is an Explanation of Benefits form issued by the injured countermeasure recipient's health insurance company.

Third-party payers of benefits for lost employment income include, but are not limited to, the injured countermeasure recipient's employer, disability insurance, workers' compensation programs, and the Department of Veterans Affairs. In order to satisfy his or her obligations under § 110.61, an injured countermeasure recipient 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 programs or payments for lost wages.

Survivors seeking death benefits will have to submit different documentation concerning third-party payers depending on whether they are seeking death benefits under the standard calculation described in § 110.82(b) or are choosing a death benefit under the alternative calculation described in § 110.82(c). 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 existing or potential third-party payers (described fully in the death benefits calculation section of this preamble and set forth in § 110.82(d)(3)(A)). Survivors seeking death benefits also must submit other documentation described in § 110.62.

Before payments will be made, the representatives of requesters who are minors or adults who lack legal capacity to receive payments must submit additional documentation described in § 110.63. Because some of this documentation may be time-consuming to obtain (*e.g.*, obtaining a court decree establishing a guardianship of the estate for an adult who lacks legal capacity), the requester may wait until a benefits calculation has been made, and a written approval has been issued, before submitting such documentation.

Determinations the Secretary Must Make Before Benefits Can Be Paid (§ 110.70 - § 110.74)

When the Secretary receives a completed and signed Request Form or Request Package postmarked within the filing deadline, she will conduct two separate reviews, as described in § 110.70. First, she will determine whether the requester is eligible for Program benefits. Second, the Secretary will determine the type and amount of any benefits that may be paid.

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 § 110.71. 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 § 110.71 as a substitute for the unavailable documentation.

If the Secretary determines that a requester is not eligible for benefits under the Program, she will inform the requester (or his or her representative) of the disapproval in writing. As described in § 110.72(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, she 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 she 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 § 110.71 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.

As set out in § 110.73, once the Secretary has calculated the amount of the benefits and determined that payment is to be made, she will inform the requester of the approval in writing and then initiate payment. Under § 110.74, if the Secretary disapproves a Request, which the Secretary may do at any time, she will so notify the requester (or his or her representative) in writing and provide information as to the requester's right to seek reconsideration of the Secretary's decision.

Payment of All Benefits Under the Program (§ 110.83)

The Secretary's options in paying all benefits under the Program are described in § 110.83. The Secretary makes all payment decisions, consistent with applicable law, and unilaterally determines the method of payment. 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 § 110.82(c)) 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, a trust such as a U.S. grantor reversionary trust, annuity or medical insurance policy, or appropriate structured settlement agreement (or a combination of these methods), provided they are 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 § 110.83(a), lump sum payments will generally be made through electronic funds transfers to requesters' accounts. Under § 110.83(b), if a requester is a minor, the payment will be made on the minor's behalf 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). Such legal guardians are also required to provide to the Secretary documentation of guardianship or conservatorship; however, the Secretary may waive this requirement for good cause. Section 110.83(b) describes the requirements pertaining to lump sum payments made on behalf of adults who lack the legal capacity to receive payments.

As provided in § 110.83(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) to give 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 unavailable under the Program.

The Tax Consequences of Receiving Benefits from the Program

The Secretary is asking the Internal Revenue Service (IRS) to provide prompt guidance on the tax consequences of receiving benefits under the Program. The Program will share this guidance as soon as it is received.

The Secretary's Right To Recover Benefits Paid Under this Program From Third-Party Payers (§ 110.84)

As described above, the payment of benefits under this Program is secondary to benefits available from other third-party payers. The category of third-party payers 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 payers are discussed in the sections of the preamble concerning the different types of benefits. As described in § 110.84, after the Secretary pays benefits under this Program, she will be subrogated to the rights of the requester, meaning that the Secretary may assert a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits. The Secretary may recover from such a third-party payer the amount of benefits the third-party payer has (or had) an obligation to pay for (or provide) or may recover them from the requester if they were paid to the requester. 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 \$5,000 (because the Secretary, as the secondary payer, would only be obligated to pay

the requester \$5,000 in benefits for lost employment income). No benefits paid under this Program are subject to any lien by any third-party payer.

Reconsideration of the Secretary's Eligibility and Benefits Determinations (§ 110.90)

Every individual who has filed a Request Package and has received a determination by the Secretary either disapproving eligibility for benefits or denying a category or amount of benefits requested has a right to seek reconsideration of the Secretary's determination(s). However, no reconsiderations may be filed concerning the mechanisms of payment.

Although such initial determinations are characterized as Secretarial determinations, this decision-making authority will be delegated to the Program. The requester or his or her representative must send a letter seeking reconsideration to the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, at the address provided in § 110.90(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 determination should be reconsidered. No new documentation may be included with this letter.

The Associate Administrator, Healthcare Systems Bureau, will convene a panel to review all cases seeking reconsideration. The panel will consist of qualified individuals who are independent of the Program. The panel will review the documentation 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 record, the panel will make a recommendation to the Associate Administrator, Healthcare Systems 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 Additional Judicial or Administrative Review of Determinations Made Under This Regulation (§ 110.91, § 110.92)

In accordance with section 262(f)(1) of the PHS Act (SEPPA) (42 U.S.C. § 239a(f)(1)) and as described in § 110.91, the PREP Act authorizes the Secretary to review at any time, on her own motion or on application, any determination made concerning eligibility, and the calculation and amount of benefits under the Program and authorizes the Secretary to affirm, vacate, or modify such determination in any manner the Secretary deems appropriate. The decision of whether to engage in such a review rests within the complete discretion of the Secretary.

However, as explained in § 110.92, 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, the PREP Act, referencing section 262(f)(2) of the PHS Act (SEPPA) (42 U.S.C. § 239a(f)(2)), 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.

Finally, there is also no judicial review of the Secretary's determinations establishing or amending a Covered Countermeasure Injury Table.

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

Through the enactment of the PREP Act, the Secretary was authorized to establish and administer the Program. Congress authorized the Secretary to issue regulations implementing the PREP Act as the Secretary deems reasonable and necessary. 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 public health pandemic, epidemic, or security threats. The sooner this regulation is in effect, the sooner the Program can be implemented and potential requesters who may have been seriously injured by a covered countermeasure will be able to be considered for medical and lost employment income benefits. Further, survivors of those who they believe have died as a result of a covered countermeasure will be able to apply for death benefits. Once this implementing regulation is in effect, the Secretary expects individuals who believe that they may be eligible for benefits under the Program will file requests for such benefits within a short time frame since Letters of Intent to request benefits have already been filed with the Program. In addition, publishing this regulation promptly is necessary to make the

remedies afforded by this Program available to potential requesters as soon as possible given the governing one year filing deadline. As noted above, the Secretary has made every effort to enable those who suffer covered injuries as the result of covered countermeasures to have an opportunity to apply for benefits under this Program. As described above, to the extent that scientific evidence linking a covered countermeasure to an injury becomes available and such injury is added to a Table, potential requesters will be able to take advantage of an alternative filing deadline, which may increase the likelihood that their Request Forms will be timely filed. In addition, the Secretary may rely upon constructive receipt of filing, as described in § 110.42(e). The Secretary further believes that her omission of a Notice of Proposed Rulemaking and delay of the effective date of this regulation is warranted given that most of the eligibility and benefits criteria under this Program are the same as those included in the SVICP's administrative implementation regulations - 42 CFR part 102. Public comments with respect to those regulations were solicited, received, and considered by the Secretary. 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 in this interim final rule will be accepted at the above listed address for a period of 60 days following the rule's publication 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

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, medical, lost employment income, and/or death 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 PREP Act. 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, to receive benefits under the Program. In the event that an otherwise eligible injured countermeasure recipient 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, how benefits will be calculated, and the documentation

that must be submitted.

Paperwork Reduction Act of 1995:

Collection of Information: The Countermeasures Injury Compensation Program

Description of Respondents: The respondents will be individuals who sustain serious injuries as a direct result of the administration or use of covered countermeasures (*i.e.*, injured countermeasure recipients) identified by the Secretary in declarations issued under the PREP Act. In addition, respondents may also be certain survivors of individuals who died as the direct result of their covered injuries or their health complications (*i.e.*, eligible survivors of deceased injured countermeasure recipients) and/or the estates of deceased injured countermeasure recipients. Examples of currently covered countermeasures are: the 2009 H1N1 vaccine, the influenza antiviral drugs Tamiflu® and Relenza® when used for pandemic purposes, pandemic influenza diagnostics, personal respiratory devices (*e.g.*, N-95 filtering facepiece respirators to prevent the spread of the 2009 H1N1 virus), and respiratory support devices (*e.g.*, ventilators used for life support for critically ill patients with respiratory failure due to infection with 2009 H1N1 virus), the influenza intravenous antiviral drug peramivir when used to treat infection with 2009 H1N1, and certain anthrax, smallpox, botulism, and acute radiation syndrome countermeasures.

Estimated Annual Reporting: The estimated annual reporting for this data collection is a total of five hours for reviewing and completing the Countermeasures Injury Compensation Program Request for Benefits Form (Request Form) and the Countermeasures Injury Compensation Program Authorization for Use or Disclosure of Health Information Form (Authorization for Health Information Form) as well as the time to obtain and provide medical and financial documentation for eligibility and the computation of benefits. The respondents listed above will

complete the Request Form to inform the CICP of their contact information (*e.g.*, name, address), and the dates and the circumstances under which a covered countermeasure was administered or used. After submitting the Request Form, the eligible respondents listed above will complete the Authorization for Health Information Form to request that medical records be sent to the CICP. The wage rate is the October 2009 average hourly earnings from the Bureau of Labor Statistics, U.S. Department of Labor. 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 for Benefits Form and Supporting Documentation	2,520	1	5	12,600	\$18.72	\$235,872
Authorization for Use or Disclosure of Health Information Form	2,520	1	1	2,520	\$18.72	\$47,174

As a result of the 2009 H1N1 influenza outbreak, this is the first time that covered countermeasures identified in PREP Act declarations are being distributed, administered, and used in the general population of the United States. This is also the first time that the strain of 2009 H1N1 virus has circulated in the United States and worldwide, and the first time that a specific influenza vaccine is available to prevent its illness. In light of these factors, the incidence of potential adverse events associated with this vaccine cannot be predicted. However, as the same technology is utilized in the production of seasonal influenza vaccine, the rate of vaccine-associated adverse events is not expected to be any different than for seasonal influenza vaccine. Since the behavior of the 2009 H1N1 virus may be unpredictable and the number of people who will get the 2009 H1N1 vaccine is unknown, the CICIP estimates of the number of Request for Benefits Forms that will be filed are predicated on currently available information. The CICIP expects that individuals with severe injuries are more likely to file requests for benefits since they may have incurred more unreimbursable medical expenses and have more lost employment income than individuals alleging less serious injuries (for whom the benefits available under the CICIP may be limited). Therefore, the estimates of Requests for Benefits assumes that a larger percentage of the more seriously injured will file for Request Packages.

According to the Centers for Disease Control and Prevention (CDC) 127 million doses of 2009 H1N1 vaccine had been distributed to public health agencies and healthcare providers in the United States as of May 28, 2010. Currently, it is estimated that approximately 90 million Americans have been vaccinated, although the precise number is not known. As of May 29, 2010, the Vaccine Adverse Reporting System (VAERS) has received 11,180 reports related to 2009 H1N1 vaccination. The vast majority (92.2% percent) of adverse events reported to VAERS after receiving the 2009 H1N1 vaccine have not involved serious health problems or outcomes (*e.g.*, they encompass events such as soreness at the vaccine injection site). Of the 11,180 reports, 868 (7.7 percent) were reports that involved what would be considered serious health events as defined by VAERS. The number of these reports is similar to those historically seen after distribution of a similar number of seasonal flu vaccine doses. Among the 11,180 reports of adverse events, there were 60 reports of deaths. The 60 VAERS reports that involve deaths are under review by CDC, the Food and Drug Administration (FDA) and the States in which the reported deaths occurred. VAERS has received 143 reports of Guillain-Barré Syndrome (GBS), for which follow-up assessments are underway. In the United States, about 80-160 cases of GBS are expected to occur each week, regardless of vaccination. VAERS is a national passive reporting system for vaccine adverse events managed by both CDC and the Food and Drug Administration (FDA) in which reports are submitted voluntarily by people who think an adverse event occurred after vaccination. VAERS accepts reports from all sources. VAERS is useful as a signal detection system to monitor for potential vaccine safety problems.

As outlined above, VAERS has received 868 serious reports and 10,312 non serious reports. Very little 2009 H1N1 vaccine is currently being administered so it can be assumed these numbers may increase slightly but will not change significantly. The CICP expects 75

percent (or 651) of these reports to result in Requests for Benefits filed with the CICP, and about 5 percent (or 516) of the reports of less serious injuries to result in Requests for Benefits with the CICP, for a total of 1,167 Requests.

In April, 2009 there were an estimated 50 million courses of FDA approved antiviral drugs in the Strategic National Stockpile (SNS). Eleven million of these 50 million were distributed to project areas (i.e., all U.S. states, territories and jurisdictions). An additional 23 million courses of antiviral drugs were purchased by project areas and held as part of state stockpiles available for distribution to the local level if needed. Assuming all the antiviral drugs provided by the SNS (approximately 11 million courses) and the state purchased antiviral drugs (approximately 23 million courses) were distributed to the local level and dispensed, the CICP expects that approximately 672 Request for Benefits Forms will be filed concerning serious injuries allegedly resulting from covered antivirals. Based on estimates by CICP staff, the incidence of very serious injuries from antivirals may be 2 in 10 million (10 cases) for anaphylaxis, 1 in 1 million (50 cases) for Toxic Epidermal Necrolysis/Stevens Johnson Syndrome, and 10 in 1 million (500 cases) for bronchospasms. The incidence of less serious injuries from antivirals is 1 in 1 million (50 cases) for skin reactions and 100 in 1 million (5,000 cases) for vomiting. The CICP estimates that 75 percent of 560 (or 420) of the individuals alleging serious injuries as a result of antivirals qualifying as covered countermeasures will file requests for benefits with the CICP. However, the CICP expects that only 5 percent of 5,050 (or 252) of the individuals alleging less serious injuries will file Request Packages with the CICP because the benefits available to them may be limited.

Certain ventilators used for life support of critically ill patients with 2009 H1N1 infection are covered countermeasures. Critically ill patients with pneumonia and respiratory

failure due to 2009 H1N1 infection require invasive mechanical ventilators to assist them with breathing. Many critically ill 2009 H1N1 patients in the intensive care unit require invasive mechanical ventilation for several weeks. Prolonged ventilator use is associated with serious adverse events such as Ventilator Associated Pneumonia (VAP), which has a high mortality rate. The CDC estimates that about between 183,000 and 378,000 H1N1-related hospitalizations occurred from April 2009-January 16, 2010. The mid-level in this range of 2009 H1N1-related hospitalizations is about 257,000. CDC further estimates that the 2009 H1N1-related deaths which occurred between April 2009 and January 16, 2010 to be about between 8,330 and 17,160. The mid-level in this range of 2009 H1N1-related deaths is about 11,690. (The CIGP expects that these individuals were hospitalized before their deaths). The CIGP estimates that 5 percent of the mid-level (or 12,850) of the individuals hospitalized ended up in the intensive care unit and 25 percent (or 3,213) of them were be placed on ventilators. About 10 percent of the 3,213 (or 321) got VAP and the CIGP estimates that 5% (or 16) will file request for benefits. Using the mid-level range for H1N1 related deaths, the CIGP estimates that 25 percent (or 2,922) were placed on ventilators and about 10 percent (or 292) of them got VAP. The CIGP estimated that 5 percent (or 15) of the survivors or the estates of those that have died as a result of the 2009 H1N1 virus may submit requests for benefits alleging that a death was caused by a ventilator. Whether such requests will result in the receipt of benefits depends on many factors, including whether the administration or use of such ventilators met the requirements of the applicable PREP Act declaration (or that a good faith belief of such existed) and whether it is demonstrated that a covered injury was sustained.

A total of 85 million N-95 filtering facepiece respirators were distributed to project areas, with an initial distribution of 25 million occurring in April 2009, and a second distribution of 60

million occurring in October, 2009. However, it is impossible to estimate how many were actually distributed by individual project areas.

In 2009, the Department of Defense (DoD) provided smallpox vaccinations to 176,068 persons which is about four times the number of civilians (39,566) that received the smallpox vaccine between January 2003 and June 2004 when healthcare and emergency workers were receiving the vaccine to prepare to respond to emergency situations. Approximately 65 of the 39,566 civilians filed requests for benefits with the Smallpox Vaccine Injury Compensation Program (SVICP), which ended in January 2008, for injuries that they sustained after being administered the smallpox vaccine. The CICP is using the experience with the SVICP to derive its estimates of the number of requests for benefits that may be filed with the CICP for injuries from the smallpox vaccine. The CICP estimates that since four times as many military personnel received this vaccine as civilians, about four times as many individuals who filed claims with the SVICP will file claims with the CICP (because military personnel were generally not eligible to receive benefits under the SVICP, but may be eligible to receive benefits under the CICP). . Therefore, the CICP estimates that about 260 Requests for Benefits for injuries from the smallpox vaccine will be filed.

In 2009, DoD immunized 224,057 individuals with anthrax vaccinations. Since the anthrax vaccine is as reactogenic as the smallpox vaccine, the SVICP experience is used to derive the estimates of the number of request for benefits that will be filed with the CICP for injuries from the anthrax vaccine. About six times the number of military personnel (224,057) received the anthrax vaccine as healthcare and emergency workers who received the smallpox vaccine per year. Therefore, the CICP estimates that about 6 times as many individuals who filed claims with the SVICP will file claims relating to the anthrax vaccine with the CICP. The

CICP estimates that about 390 requests for benefits for injuries from the anthrax vaccine will be filed. It is important to note that these estimates do not reflect the Secretary's assessment of the actual number of serious injuries or deaths resulting from the covered countermeasures described here. VAERS is a passive reporting system and has inherent limitations. Although it is a useful resource to generate hypotheses, it cannot be relied on to reach conclusions concerning the numbers of serious injuries or deaths actually resulting from particular vaccines. Moreover, even if the injuries are indeed serious and are determined by the Secretary to have resulted from a covered countermeasure, requesters with the CICP may still be deemed ineligible for benefits (for example, the person using a covered countermeasure may not have satisfied all of the specifications of the pertinent PREP Act declaration, the Request Form might have been filed outside of the one year filing deadline).

Comments on this information collection activity should be sent to INSERT NAME, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, 725 17th Street, NW., Washington, DC 20053; Fax: (202) 395-INSERT NUMBER.

List of Subjects in 42 CFR Part 110

Benefits, Biologics, Compensation, Immunization, Public Health, Pandemic, Countermeasures, Pandemic Influenza, 2009 H1N1 Vaccine, Influenza Antivirals, Tamiflu®, Relenza®, peramivir, Pandemic Influenza Diagnostics, Personal Respiratory Devices, N-95 Filtering Facepiece Respirators, Respiratory Support Devices, Ventilators, Anthrax, Smallpox, Botulism, Acute Radiation Syndrome.

Dated:

Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration

Approved:

Kathleen Sebelius
Secretary

For the reasons stated in the preamble, the Department amends part 110 of 42 CFR as follows:

1. The authority section for part 110 is revised to read as follows:

Authority: 42 U.S.C. 247d-6e.

2. In part 110, add sections 110.1-110.110 to read as follows:

PART 110--COUNTERMEASURES INJURY COMPENSATION PROGRAM Subpart A--
General Provisions. 110.1 Purpose. 110.2 Summary of available benefits. 110.3 Definitions.
Subpart B--Persons Eligible to Receive Benefits. 110.10 Eligible requesters. 110.11 Survivors.
Subpart C--Covered Injuries. 110.20 How to establish a covered injury. Subpart D--Available
Benefits. 110.30 Benefits available to different categories of requesters under this Program.
110.31 Medical benefits. 110.32 Benefits for lost employment income. 110.33 Death benefits.
Subpart E--Procedures for Filing Request Packages. 110.40 How to obtain forms and
instructions. 110.41 How to file a Request Package. 110.42 Deadlines for filing Request Forms.
110.43 Deadlines for submitting documentation. 110.44 Legal or personal representatives of
requesters.
110.45 Multiple survivors. 110.46 Amending a request package. Subpart F-- Documentation
Required for the Secretary to Determine Eligibility. 110.50 Medical records necessary for the
Secretary to determine whether a covered injury was sustained. 110.51 Documentation an
injured countermeasure recipient must submit for the Secretary to make a determination of
eligibility for Program benefits. 110.52 Documentation a survivor must submit for the Secretary
to make a determination of eligibility for death benefits. 110.53 Documentation the executor or
administrator of the estate of a deceased injured countermeasure recipient must submit for the
Secretary to make a determination of eligibility for benefits to the estate. Subpart G--
Documentation Required for the Secretary to Determine Program Benefits. 110.60

Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits. 110.61 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of lost employment income benefits. 110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits. 110.63 Documentation a legal or personal representative must submit when filing on behalf of a minor or on behalf of an adult who lacks legal capacity to receive payment of benefits. Subpart H--Secretarial Determinations. 110.70 Determinations the Secretary must make before benefits can be paid. 110.71 Insufficient documentation for eligibility and benefits determinations. 110.72 Sufficient documentation for eligibility and benefits determinations. 110.73 Approval of benefits. 110.74 Disapproval of benefits. Subpart I--Calculation and Payment of Benefits. 110.80 Calculation of medical benefits. 110.81 Calculation of benefits for lost employment income. 110.82 Calculation of death benefits. 110.83 Payment of all benefits. 110.84 The Secretary's right to recover benefits paid under this Program from third-party payers. Subpart J--Reconsideration of the Secretary's Determinations. 110.90 Reconsideration of the Secretary's eligibility and benefits determinations. 110.91 Secretary's review authority. 110.92 No additional judicial or administrative review of determinations made under this part.

PART 110--COUNTERMEASURES INJURY COMPENSATION PROGRAM

Subpart A--General Provisions

Sec.

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110.2 Summary of available benefits.

110.3 Definitions.

Subpart B--Persons Eligible to Receive Benefits

110.10 Eligible requesters.

110.11 Survivors.

Subpart C--Covered Injuries

110.20 How to establish a covered injury.

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110.30 Benefits available to different categories of requesters under this Program.

110.31 Medical benefits.

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Subpart E--Procedures for Filing Request Packages

110.40 How to obtain forms and instructions.

110.41 How to file a Request Package.

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110.44 Legal or personal representatives of requesters.

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Subpart F-- Documentation Required for the Secretary to Determine Eligibility

110.50 Medical records necessary for the Secretary to determine whether a covered injury was sustained.

110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.

110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.

110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

Subpart G--Documentation Required for the Secretary to Determine Program Benefits

110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.

110.61 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of lost employment income benefits.

110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits.

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110.90 Reconsideration of the Secretary's eligibility and benefits determinations.

110.91 Secretary's review authority.

110.92 No additional judicial or administrative review of determinations made under this part.

Subpart K--Covered Countermeasures Injury Tables

110.100 (Reserved)

Subpart A--General Provisions

§ 110.1 Purpose.

This part implements the Public Readiness and Emergency Preparedness Act (PREP Act), which amended the Public Health Service Act (herein after “PHS Act” or “the Act”) by including section 319F-3, and section 319F-4 entitled “Covered Countermeasure Process.” Section 319F-4 of the PHS Act directs the Secretary of Health and Human Services, following issuance of a declaration under section 319F-3(b), to establish procedures for the Countermeasures Injury Compensation Program (herein after “CICP” or “the Program”) to provide medical and lost employment income benefits to certain individuals who sustained a covered injury as the direct result of the administration or use of a covered countermeasure consistent with a declaration issued pursuant to section 319F-3(b), or in the good faith belief that administration or use of the covered countermeasure was consistent with a declaration. Also, if the Secretary determines that an individual died as a direct result of a covered injury, the Act provides for certain survivors of that individual to receive death benefits.

§ 110.2 Summary of available benefits.

(a) The Act authorizes three forms of benefits to, or on behalf of, requesters determined to be eligible by the Secretary:

(1) Payment or reimbursement for reasonable and necessary medical services and items to diagnose or treat a covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31.

(2) Lost employment income incurred as a result of a covered injury, as described in § 110.32.

(3) Death benefits to certain survivors if the Secretary determines that the death of the injured countermeasure recipient was the direct result of a covered injury, as described in § 110.33.

(b) In general, the benefits paid under the Program, are secondary to any obligation of any third-party payer to provide or pay for such benefits. The benefits available under the CICP usually will be paid only after the requester has in good faith attempted to obtain all other available coverage from all third-party payers with an obligation to pay for or provide such benefits (*e.g.*, medical insurance for medical services or items, workers' compensation program(s) for lost employment income). However, as provided in § 110.84, the Secretary has the discretion to pay benefits under this Program before a potential third-party payer makes a determination on the availability of similar benefits and has the right to later pursue a claim against any third-party payer with a legal or contractual obligation to pay for, or provide, such benefits.

§ 110.3 Definitions.

This section defines certain words and phrases found throughout this part.

(a) *Act* or *PHS Act* means the Public Health Service Act, as amended.

(b) *Approval* means a decision by the Secretary or her designee that the requester is eligible for benefits under the Program.

(c) *Alternative calculation* means the calculation used in § 110.82(c) of this part for the death benefit

available to dependents younger than 18 years old at the time of payment.

(d) *Benefits* means payments and/or compensation for reasonable and necessary medical expenses or provision of services described in § 110.31, lost employment income described in § 110.32, and/or payment to certain survivors of death benefits described in § 110.33.

(e) (1) *Child* means any natural, illegitimate, adopted, posthumous child, or stepchild of a deceased injured countermeasure recipient who, at the time of the countermeasure recipient's death is:

(A) 18 years of age or younger; or

(B) Between 19 and 22 years of age and a full-time student; or

(C) Incapable of self-support due to a physical or mental disability.

(2) *Posthumous child* means a child born after the death of the parent.

(3) *Stepchild* means a child of an injured countermeasure recipient's spouse but who is not the child of the injured countermeasure recipient. For a stepchild to be eligible for survivor death benefits under the Program, the stepchild's parent must have been married to the injured countermeasure recipient at the time of that injured countermeasure recipient's death, and the stepchild must have been supported by the injured countermeasure recipient.

(f) *Covered countermeasure* means the term that is defined in section 319F-3(i)(1) of the PHS Act and described in a declaration issued under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(i)(I), (b)).

To be a covered countermeasure for purposes of this part, the countermeasure must have been administered or used:

(1) Pursuant to the terms of a declaration, or in a good faith belief that it was so administered or used; and

(2) Within a State (as defined in § 110.3(aa)), otherwise in the territory of the United States, or in places over which the United States has sovereignty or some measure of legislative control.

(g) *Covered injury* means death, or a serious injury as described in § 110.20(b), and determined by the Secretary in accordance with § 110.20 of this part, to be:

(1) An injury meeting the requirements of a Covered Countermeasures Injury Table, which is presumed to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or

(2) An injury (or its health complications) that is the direct result of the administration or use of a covered countermeasure. This includes serious aggravation caused by a covered countermeasure of a pre-existing condition.

(h) *Declaration* means a recommendation issued by the Secretary under section 319F-3(b) of the PHS Act (42 U.S.C. 247d-6d(b)), for the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, following her determination that a specific disease, condition, or threat represents a public health emergency or a credible risk of a future public health emergency.

(i) *Dependent* means, for purposes of lost employment income benefits, a person whom the Internal Revenue Service would consider to be the injured countermeasure recipient's dependent at the time the covered injury was sustained. For purposes of survivor death benefits, *dependent* means a person whom the Internal Revenue Service would consider to be the deceased injured countermeasure recipient'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.

(j) *Disapproval* means a decision by the Secretary that the individual requesting benefits is not eligible to receive benefits under the Program for the specified injury that is the basis of the Request for Benefits.

(k) *Effective period of the declaration* means the time span specified in a declaration, or as amended by

the Secretary.

(l) *Federal Employees' Compensation Act (FECA) Program* means the workers' compensation benefits program for civilian officers and employees of the Federal Government established under 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) *Healthcare provider* means an individual licensed, certified, or registered by an appropriate authority and who is qualified and authorized to provide health care services, such as diagnosing and treating physical or mental health conditions, prescribing medications, and providing primary and/or specialty care.

(n) *Injured countermeasure recipient* means an individual:

(1) Who, with respect to administration or use of a covered countermeasure pursuant to a Secretarial declaration:

(A) Meets the specifications of the pertinent declaration; or

(B) Is administered or uses a covered countermeasure in a good faith belief that he or she is in a category described by subparagraph (A); and

(2) Sustained a covered injury as defined in section 110.3(g).

(3) If a covered countermeasure is administered to, or used by, a pregnant woman in accordance with paragraphs (1)(A) or (1)(B), any child from that pregnancy who survives birth is an injured countermeasure recipient if the child is born with, or later sustains, a covered injury (as defined in section 110.3(g)) as the direct result of the covered countermeasure's administration to, or use by, the mother during her pregnancy.

(o) *Lacks legal capacity* means legally incompetent to receive payment(s) of benefits, as determined under applicable law.

- (p) *Medical records* means documentation associated with primary care, hospital in-patient and out-patient care, specialty consultations, and diagnostic testing and results.
- (q) *Payer of last resort* means that the Program pays benefits secondary to all other public and private third-party payers who have an obligation to pay for such benefits.
- (r) *Program* means the Countermeasures Injury Compensation Program (CICP).
- (s) *PREP Act* means the *Public Readiness and Emergency Preparedness Act*, codified as sections 319F-3 and 319F-4 of the PHS Act (42 U.S.C. 247d-6d, 42 U.S.C. 247d-6e).
- (t) *Public Safety Officers' Benefits (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.
- (u) *Representative* (legal or personal) means someone other than the person for whom Program benefits are sought, and who is authorized to file the Request Package on the requester's behalf pursuant to § 110.44.
- (v) *Requester* means an injured countermeasure recipient, or survivor, or the estate of a deceased injured countermeasure recipient (through the executor or administrator of the estate) who files a Request Package for Program benefits, or on whose behalf a Request Package is filed, under this part.
- (w) *Request Form or Request for Benefits Form* means the document designated by the Secretary for applying for Program benefits under this part.
- (x) *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 Program eligibility and benefits under this part.
- (y) *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 conferred on the Secretary under the PREP Act has been delegated.

(z) *Serious injury* means serious physical injury. Physical biochemical alterations leading to physical changes and serious functional abnormalities at the cellular or tissue level in any bodily function may, in certain circumstances, be considered serious injuries. As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability (whether or not hospitalization was warranted) will be considered serious injuries.

(aa) *Standard calculation* means the calculation used in § 110.82(b) of this part for the death benefit available to all eligible survivors (other than surviving dependents younger than the age of 18 who do not fit the definition of “child” under § 110.3(e)).

(bb) *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.

(cc) *Survivor* means a person meeting the requirements of § 110.11 with respect to a deceased injured countermeasure recipient who died as a direct result of a covered injury.

(dd) *Table or Table of Injuries* means a Table of Covered Countermeasure Injuries to be included under Subpart K of this part, including the definitions and requirements set out therein.

(ee) *Third-party payer* means the United States (other than for payments of benefits under this Program) or any other third party, including but not limited to, any State or local governmental entity, private insurance carrier, or employer, any public or private entity with a legal or contractual obligation to pay for or provide benefits. The Program is the payer of last resort.

Subpart B--Persons Eligible To Receive Benefits

§ 110.10 Eligible requesters.

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

- (1) Injured countermeasure recipients, as described in § 110.3(n);
- (2) Survivors, as described in § 110.3(cc) and § 110.11; or
- (3) Estates of deceased injured countermeasure recipients through individuals authorized to act on behalf of the deceased injured countermeasure recipient's estate under applicable State law (*i.e.*, executors or administrators).

(b) If a countermeasure recipient dies, his or her survivor(s) and/or the executor or administrator 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 injured countermeasure recipient, but must be filed within the filing deadlines described in § 110.42. Amendments to previously filed Request Packages and the filing deadlines for such amendments are described in § 110.46.

(c) The benefits available to different categories of requesters are described in § 110.30.

§ 110.11 Survivors.

(a) *Survivors of injured countermeasure recipients who died as the direct result of a covered injury.* If the Secretary determines that an injured countermeasure recipient 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 the 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 have satisfied the eligibility requirements for a deceased public safety officer, whereas the person who is survived under this Program must be a deceased injured countermeasure recipient 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 countermeasure recipient 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 countermeasure recipient 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 § 110.82(c), and is not eligible to receive death benefits under the standard calculation described in § 110.82(b). Death benefits paid under the alternative calculation will be paid to the dependents' legal guardian(s) on behalf of all such 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

§ 110.20 How to establish a covered injury.

(a) *General.* Only serious injuries, as described in §110.3(z), or deaths are covered under the Program. In order to be eligible for benefits under the Program, a requester must submit documentation showing that a covered injury, as described in §110.3(g), was sustained as the direct result of the administration or use of a covered countermeasure pursuant to the terms of a declaration under section 319F-3(b) of the PHS Act (including administration or use during the effective period of the declaration) *or* as the direct result of the administration or use of a covered countermeasure in a good faith belief that it was administered or used pursuant to the terms of a declaration (including administration or use during the effective period of the declaration). 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, as described in paragraph (d) of this section. The Secretary may obtain the opinions of qualified medical experts in making determinations concerning covered injuries.

(b) *Table injuries.* A Table lists and explains injuries that, based on compelling, reliable, valid, medical and scientific evidence, are presumed to be caused by a covered countermeasure, and the time periods in which the onset (*i.e.*, first sign or symptom) of these injuries must occur after administration or use of the covered countermeasures. If an injury occurred within the listed time periods, and at the level of severity required, there is a rebuttable presumption that the covered countermeasure was the cause of the injury. A Table is accompanied by Qualifications and Aids to Interpretation which provide an

explanation of the injuries listed on a Table. A requester may establish that a covered injury occurred by demonstrating that the countermeasure recipient sustained an injury listed on a Table, within the time interval defined by the Table's Definitions and Requirements. 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 or use of a covered countermeasure. Even if the Table requirements are satisfied, however, an injury will not be considered a covered injury if the Secretary determines, based on her review of the evidence, that a source other than the countermeasure more likely caused the injury. In such circumstances, the Table presumption of causation will be rebutted.

(c) *Injuries for which causation must be shown (non-Table injuries)*. If an injury is not included on a Table or if the injury does not meet the requirements set out for an injury that is listed on a Table (*e.g.*, the first sign or symptom of the injury did not occur within the time interval specified on the Table), the requester must demonstrate that the injury occurred as the direct result of the administration or use of a covered countermeasure. Such proof must be based on compelling, reliable, valid, medical and scientific evidence. Temporal association between receipt of the countermeasure and onset of the injury is not sufficient by itself to prove that the countermeasure caused the injury.

(d) An injury sustained as the direct result of the covered condition or disease for which the countermeasure was administered or used, and not as the direct result of the administration or use of the covered countermeasure, is not a covered injury (*e.g.*, if the covered countermeasure is ineffective in treating or preventing the underlying condition or disease).

Subpart D--Available Benefits

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

(a) *Benefits available to injured countermeasure recipients*. A requester who is an injured

countermeasure recipient may be eligible 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 deceased injured countermeasure recipient may be eligible to receive a death benefit if the death was caused by the covered injury or its health complications.

(c) *Benefits available to estates of deceased injured countermeasure recipients.* The estate of an otherwise eligible deceased injured countermeasure recipient may be eligible to receive medical benefits or benefits for lost employment income, or both, if such benefits were accrued during the deceased countermeasure recipient's lifetime, or at the time of death, as a result of a covered injury or its health complications, but have not yet been paid in full by the Program. Such medical benefits and benefits for lost employment income may be available regardless of the cause of death. The estate of the deceased injured countermeasure recipient may not receive a death benefit. Death benefits are only available to certain survivors.

§ 110.31 Medical benefits.

(a) Injured countermeasure recipients 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 to diagnose, treat, or prevent the health complications of a covered injury. 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 any health complication of a covered injury, or to give relief, reduce the degree or the period of disability, or aid in lessening the amount of 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 reasonable and necessary medical services and items have already been provided or if they are likely to be needed 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 healthcare provider, and may consider whether the applicable service or item is within the standard of care for that condition.

(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, ill-effects that stem from the covered injury, an adverse reaction to a prescribed medication or as a result of a 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 § 110.80. Although there are no caps on medical benefits, the Secretary may limit payments to the amounts that she determines are reasonable for services and items considered reasonable and necessary. All payment or reimbursement for medical services and items is secondary to any obligation of any third-party payer to pay for or provide such services or items to the requester. As provided in § 110.84, the Secretary retains the right to recover medical benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits. Requesters are expected to make good faith efforts to pursue medical benefits and services from their primary payers. The Secretary reserves the right to disapprove medical benefits if the requester fails to do so.

(d) The Secretary may make payments of medical benefits or reimbursements of medical expenses described in this section to the estate of a deceased injured countermeasure recipient as long as such payments or expenses were accrued during the deceased injured countermeasure recipient's lifetime, or at the time of death, as the result of the covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died.

§ 110.32 Benefits for lost employment income.

(a) Requesters who are determined to be eligible for Program benefits as injured countermeasure recipients 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 § 110.31(b)). Compensation for lost wages is paid as a percentage of the amount of employment income earned at the time of injury and lost as the result of the covered injury or its health complications. The period of time requested for lost employment income benefits must be supported by the severity of the covered injury as demonstrated by the medical and employment records.

(b) The method and amount of benefits for lost employment income are described in § 110.81. Benefits for lost employment income will be adjusted if there are fewer than ten days of lost employment income. Pursuant to law, and as described in § 110.81, 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 payer to pay for lost employment income or to provide disability or retirement benefits to the requester. It is the obligation of requesters to follow all specified procedures to apply for and acquire third-party benefits. The Secretary has the discretion to disapprove lost employment income benefits if the requester fails to do so. As provided in § 110.84, the Secretary reserves the right to recover lost employment income benefits paid by the Program to requesters if third-party payers are obligated to provide those benefits.

(c) The Secretary does not require an individual to use paid leave (*e.g.*, sick leave or vacation leave) for lost work days. However, if an individual uses paid leave for lost work days, the Secretary will not consider those days to be days of lost employment income unless the individual reimburses the employer for the paid leave taken and the employer restores the leave that was used. This puts the individual back in the same position as if he or she had not used paid leave for the lost work days.

(d) The Secretary may pay benefits for lost employment income to the estate of a deceased injured

countermeasure recipient as long as such benefits were accrued during the deceased injured countermeasure recipient's lifetime as the result of a covered injury or its health complications, and were not paid in full by the Program before the deceased injured countermeasure recipient died. However, no such lost employment income may be paid after the receipt, by the survivor or survivors of a deceased injured countermeasure recipient, of death benefits under § 110.82.

§ 110.33 Death benefits.

(a) Eligible survivors may be able to receive a death benefit under this Program if the Secretary determines that an otherwise eligible countermeasure recipient sustained a covered injury and died as a direct result of the injury or its health complications. The method and amount of death benefits are described in § 110.82. As provided in § 110.84, the Secretary retains the right to recover death benefits paid by the Program if third-party payers are obligated to provide those benefits. There are two different calculations for death benefits: the standard calculation and the alternative calculation.

(b) The standard calculation, described in § 110.82(b), is based upon the death benefit available under the PSOB Program and is available to all eligible survivors with one exception (surviving dependents younger than the age of 18 who do not fit the definition of “child” under §110.3(e)). In the event that death benefits were paid under the PSOB Program with respect to the deceased injured countermeasure recipient, 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. If a disability benefit was paid under the PSOB Program, the amount of that disability benefit would be deducted from benefits payable under the standard calculation.

(c) The alternative calculation, described in § 110.82(c), is based on the injured countermeasure recipient’s employment income at the time of the covered injury. Payment under this calculation is only available to surviving dependents who are younger than the age of 18 at the time of payment. The legal

guardian(s) of such surviving dependents must select the death benefit as calculated under this alternative calculation before it will be paid. Annual and lifetime caps may apply. The payment of a death benefit as calculated under this alternative calculation is secondary to other benefits paid or payable with respect to the deceased injured countermeasure recipient, namely:

1. Compensation for loss of employment income (except for lost employment income under this Program);
2. Death or disability benefits (*i.e.*, payments including, but not limited to, those under the PSOB Program) on behalf of the dependent(s) or their legal guardian(s);
3. Retirement benefits on behalf of the dependent(s) or their legal guardians; or
4. Life insurance benefits on behalf of the dependent(s).

Subpart E--Procedures for Filing Request Packages

§ 110.40 How to obtain forms and instructions.

(a) Copies of all necessary forms and instructions will be available:

(1) By writing to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857.

(2) By calling 1-888-ASK-HRSA. This is a toll-free number.

(3) By downloading them from the Internet at <http://www.hrsa.gov/countermeasurescomp/>. Click on the link to “Forms and Instructions.”

(b) Before reviewing a Request for Benefits, the Secretary will assign a case number to the Request for Benefits 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 for Benefits will be referenced by this case number.

§ 110.41 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 benefits. Request Packages may be submitted through the U.S. Postal Service, commercial carrier, or private courier service. The Countermeasures Injury Compensation Program will not accept Request Packages that are hand-delivered. Electronic submissions are not currently accepted, but may be in the future. The Program will publish a notice if electronic filing becomes available. Requesters (or their representatives) should send all forms and documentation to the Countermeasures Injury Compensation Program, Healthcare Systems Bureau, Health Resources and Services Administration, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857. All documentation to the Program must include the case number once one has been assigned to the requester.

§ 110.42 Deadline for filing Request Forms.

(a) *General.* All Request Forms (or Letters of Intent, described in subsection (b)) must be filed within **one year** of the date of the administration or use of a covered countermeasure that is alleged to have caused the injury. If no previous Request Form (or Letter of Intent) has been filed, this deadline also applies to survivor(s) of an injured countermeasure recipient who is deceased, and to the executor or administrator of his or her estate. If a Request Form (or Letter of Intent) was previously filed, § 110.46 describes amendments to Request Packages.

(b) *Letters of Intent.* Until Request Forms and Instructions are available, requesters must file a Letter of Intent to File, in order to establish that their Requests for Benefits are timely filed within the one-year deadline. Directions for submitting a Letter of Intent (to file) are available on the Program's web site at <http://www.hrsa.gov/countermeasurescomp/> or by calling 1-888-ASK-HRSA. Even once Request Forms are available, the Secretary has the discretion to accept Letters of Intent (to file) for purposes of meeting

the filing deadline. However, when Request Forms and Instructions are available, all requesters who have submitted Letters of Intent must still file Request Forms as soon as possible.

(c) *Determination of proper filing.* The filing date is the date the Request Form (or Letter of Intent) is postmarked. A legibly dated receipt from a commercial carrier, a private courier service, or the U.S. Postal Service will be considered equivalent to a postmark. If and when Request Forms are accepted electronically, the filing date is the date the Request Form is submitted electronically. 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 personal or legal representative. After filing a Request Form within the governing filing deadline, a requester must update the Request Package to reflect new information as it becomes available (*e.g.*, copies of medical records generated after the initial submission of the Request Package).

(d) *Request Forms not filed within the one-year deadline.* If the Secretary determines that a Request Form or Letter of Intent was not filed within the governing filing deadline set out in this section, the Request Form (or Letter of Intent) will not be processed and the requester will not be eligible for benefits under this Program.

(e) *Constructive receipt.* The Secretary reserves the right to consider a legal claim filed with the Federal Government (*e.g.*, a Federal Tort Claims Act claim or a petition with the National Vaccine Injury Compensation Program) concerning an alleged injury resulting from the administration or use of a covered countermeasure to be a filing of a Request Form or Letter of Intent for purposes of determining the filing date under this Program. The date of such constructive filing will be the official filing date of the action, *i.e.*, when all applicable requirements for proper filing in that forum have been met.

(f) *Request Forms (or amendments to Request Forms) based on initial publication of a Table of Injuries or modifications to an existing Table.* The Secretary may publish a new Table (or Tables) by

amendment(s) to Subpart K of this part. The effect of such a new Table or amendment may enable a requester who previously could not establish a Table injury to do so. In such circumstances, the requester must file a new Request Form if one was previously submitted and eligibility was denied or if one was not previously submitted within one year after the effective date of the establishment of, or amendment to, the Table. If the Secretary has not made a determination, she will automatically review any pending Request Forms in light of the new or amended Table(s).

§ 110.43 Deadlines for submitting documentation.

(a) *Documentation for eligibility determinations.* 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 § 110.42. The Secretary generally will not begin review of a requester's eligibility until all the documentation necessary to make this determination has been submitted.

(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 review of the benefits available to a requester until the documentation necessary to make a benefits determination has been submitted.

§ 110.44 Legal or personal representatives of requesters.

(a) *Generally.* Persons other than a requester (*e.g.*, a lawyer, guardian, family member, friend) may file a Request Package on a requester's behalf as his or her legal or personal representative. A requester need not use the services of a lawyer to apply for benefits under this Program. A legal representative, or a personal representative (who does not need to be a lawyer) is only required, as described in this section, for requesters who are minors or adults who lack legal capacity to receive payment of benefits. In the

event that a legal or personal 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 out in this part. If a requester has a representative, the Program will generally direct all communications to the representative. However, the Secretary reserves the right of the Program to contact the requester directly if necessary, and to conduct a follow-up survey to determine the ability of the Program to meet requesters' needs.

(b) *Legal or personal representatives of legally competent adults.* A requester who is a legally competent adult *may* use a legal or personal representative to submit a Request Package on his or her behalf. In such circumstances, the requester must indicate on the Request Form that he or she is authorizing the representative to seek benefits under this Program on his or her behalf.

(c) *Legal or personal representatives of minors and adults who lack legal capacity to receive payment of benefits.* A requester who is a minor or an adult who lacks legal capacity to receive payment of benefits *must* use a legal or personal representative to apply for benefits under this Program on his or her behalf. In such circumstances, the representative must indicate, in the place provided on the Request Form, that the requester is a minor or an adult who lacks legal capacity to receive payment of benefits 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 § 110.63. A minor who is emancipated, as determined by a court of competent jurisdiction, does not need a legal or personal representative to file a Request Form or Request Package on his or her behalf.

(d) *No payment or reimbursement for legal or personal representatives' fees or costs.* The Act does not authorize the Secretary to pay for, or reimburse, any fees or costs associated with the requester's use of

the services of a legal or personal representative under this Program, including those of an attorney.

§ 110.45 Multiple survivors.

Multiple survivors of the same deceased injured countermeasure recipient 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.

§ 110.46 Amending a request package.

(a) *Generally.* All requesters may amend their documentation concerning eligibility up to the time the Secretary has made an eligibility determination. Requesters are expected to submit additional medical records as they become available. Requesters also may amend their information or documentation concerning the calculation of benefits until the Secretary has made a benefits determination. Once an *eligibility* determination has been made, the Secretary will not accept additional documentation concerning eligibility, except as described in (b) and (c) below. Once a *benefits* determination has been made, the Secretary will not accept additional documentation regarding the type or amount of benefits for that covered injury, except as described in (b) and (c) below.

(b) *Requesters who are survivors.* If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies, or the executor or administrator timely filed on behalf of the estate, the survivor(s) may amend the previously filed Request Package at any time by filing a new Request Form in order to be considered 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 injured countermeasure recipient's Request Package. However, a survivor filing an amendment to a previously filed Request Package may only be eligible for 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 injured countermeasure recipient 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 § 110.11.

(c) Requests in which the benefits are sought for the estate of a deceased injured countermeasure recipient. If an injured countermeasure recipient submitted a Request Form within the filing deadline, but subsequently dies before all due benefits are paid by the Program, the executor or administrator of his or her estate may amend his or her Request Package at any time in order for the estate to be considered for benefits. This opportunity to amend applies also if the Request Form was timely filed by a survivor. Such an amendment can be filed regardless of whether the Secretary made an eligibility determination or paid benefits with respect to the deceased injured countermeasure recipient's Request Package. However, the executor or administrator of the deceased injured countermeasure recipient's estate filing an amendment to a previously filed Request Package may only be eligible to receive benefits on behalf of the estate if the previously filed Request Package was filed within the governing deadline. All documentation that has already been submitted with respect to the deceased injured countermeasure recipient will be considered part of that person's Request Package, and the executor or administrator of the estate is not required to resubmit such documentation.

Subpart F--Documentation Required for the Secretary to Determine Eligibility

§ 110.50 Medical records necessary for the Secretary to determine whether a covered injury was sustained.

(a) In order to determine whether an injured countermeasure recipient sustained a covered injury, a requester must arrange for his or her medical providers to submit to the Program the following medical records, as defined in § 110.3(p):

- (1) All medical records documenting medical visits, procedures, consultations, and test results that

occurred on or after the date of administration or use of the covered countermeasure; and

(2) All hospital records, including the admission history and physical examination, the discharge summary, all physician subspecialty consultation reports, all physician and nursing progress notes, and all test results that occurred on or after the date of administration or use of the covered countermeasure; and

(3) All medical records for one year prior to administration or use of the covered countermeasure as necessary to indicate an injured countermeasure recipient's pre-existing medical history.

(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 introduce additional medical documentation or scientific evidence in order to establish that an injury was caused by a covered countermeasure. Letters from treating physicians may be submitted as additional evidence, but may not substitute for the medical documentation required in paragraph (a) above.

(c) If certain medical records listed in paragraph (a) of this section are unavailable to the Program after the requester has made reasonable efforts to facilitate the records being sent to the Program, the requester must submit a statement describing the reasons for the records' unavailability and the efforts he or she has made to arrange for the health care providers to submit them. The Secretary has the discretion to accept this statement in place of the unavailable medical records. In this circumstance, the Secretary may attempt to obtain the records on the requester's behalf.

(d) In certain circumstances, the Secretary may require additional records to make a determination that a covered injury was sustained (*e.g.*, medical records more than one year prior to the date of administration or use of the covered countermeasure) or may determine that certain records described in paragraph (a) of this section are not necessary for an eligibility determination.

(e) Although the Secretary prefers to receive medical records directly from healthcare providers, she has

the discretion to accept them from the requester.

§ 110.51 Documentation an injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for Program benefits.

(a) An injured countermeasure recipient (or his or her legal or personal representative) must submit all of the following documentation in order for the Secretary to make a determination of eligibility:

(1) A completed and signed Request Form submitted within the filing deadline described in § 110.42; and

(2) Records sufficient to demonstrate that the injured countermeasure recipient used or was administered a covered countermeasure; and

(3) Records sufficient to demonstrate that the injured countermeasure recipient sustained a covered injury, as defined in § 110.3(g), in accordance with the requirements set forth in § 110.50; and

(4) A copy of each signed Authorization for Health Information Form authorizing the release of records to the Program that was sent by the requester to each healthcare provider instructing that the records be submitted directly to the Program.

(b) In certain circumstances, some of the above documentation may not be required, or additional documentation may be required, in which case the Secretary will so notify the requester. For example, the Secretary may require records sufficient to demonstrate that the injured countermeasure recipient was administered or used a covered countermeasure in accordance with the provisions of a Secretarial declaration, or in the good faith belief that it was so administered or used, if she is unable to determine this from the records submitted. In order to meet the specifications of a declaration, some individuals will need to show that the activity giving rise to the injury (*i.e.*, administration or use of the covered countermeasure) was authorized in accordance with the public health and medical response of the Authority Having Jurisdiction, as defined in the pertinent declaration, to prescribe, administer, deliver,

distribute or dispense the covered countermeasure following a declaration of an emergency, as defined in the pertinent declaration. For purposes of this part, this requirement can be satisfied by showing that the covered countermeasure was administered or used following the declaration of an emergency, as defined in the pertinent declaration, by an Authority Having Jurisdiction, as defined in the pertinent declaration either: (1) pursuant to a written agreement or other formal arrangement with an Authority Having Jurisdiction; or (2) in accordance with the written recommendations of an Authority Having Jurisdiction.

§ 110.52 Documentation a survivor must submit for the Secretary to make a determination of eligibility for death benefits.

(a) A requester who is a survivor under § 110.11 must submit the following documentation in order for a determination of eligibility for a death benefit to be made:

(1) All of the documentation required for individuals in § 110.51. There is no need to duplicate documentation already submitted to satisfy the requirements of other subparts in this part. For example, if the deceased injured countermeasure recipient had previously filed, the documentation submitted does not have to be re-submitted; and

(2) A death certificate for the deceased countermeasure recipient. 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 injured countermeasure recipient is deceased; and

(3) Medical records sufficient to establish that the deceased injured countermeasure recipient died as the result of the covered injury or its health complications. Such medical records may be the same as those required under §110.50. If an autopsy was performed, the requester must submit a complete copy of the final autopsy report; and

(4) Documentation showing that the requester is an eligible survivor, pursuant to § 110.11 (*e.g.*, birth certificate or marriage certificate); and

(5) Verification, on the place provided on the Request Form, either that there are no other eligible survivors (*e.g.*, for surviving eligible children, 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 110.11 describes eligible survivors and the priorities of survivorship; and

(6) Even if a Request Form had previously been filed by the injured countermeasure recipient, the survivor(s) must submit a new Request Form.

§ 110.53 Documentation the executor or administrator of the estate of a deceased injured countermeasure recipient must submit for the Secretary to make a determination of eligibility for benefits to the estate.

(a) The executor or administrator of the estate of a deceased injured countermeasure recipient must submit the following documentation in order for a determination of eligibility for benefits to the estate to be made:

(1) All of the documentation required for individuals in § 110.51;

(2) A death certificate for the deceased injured countermeasure recipient. If a death certificate is unavailable, the executor or administrator must submit a letter providing the reasons for its unavailability. The Secretary has the discretion to accept other documentation as evidence that the injured countermeasure recipient is deceased; and

(3) Documentation showing that the individual is the executor or administrator of the estate of the deceased injured countermeasure recipient, *e.g.*, Letter of Administration issued by a court of

competent jurisdiction; and

(4) Even if a Request Form had previously been filed by the injured countermeasure recipient, the executor or administrator of the estate must submit a new Request Form.

Subpart G--Documentation Required for the Secretary to Determine Program Benefits

§ 110.60 Documentation a requester who is determined to be eligible must submit for the Secretary to make a determination of medical benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks payment or reimbursement for medical services or items must provide the following, in addition to the documentation submitted under Subpart F of this part:

(1) *List of third-party payers.* The requester must submit a list of all third-party payers that may have an obligation to pay for or provide any medical services or items to the injured countermeasure recipient for which payment or reimbursement is being sought under this Program. Such third-party payers may include, but are not limited to, health maintenance organizations, health insurance companies, workers' compensation programs, Medicare, Medicaid, Department of Veterans Affairs, military treatment facilities (MTFs), and any other entities obligated to provide medical services or items or reimburse individuals for medical expenses. Such a list must include the injured countermeasure recipient's account numbers and other applicable information. If the requester knows of no such third-party payer, he or she must so certify in writing. If the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

(2) *Documents for medical services or items provided since the onset of the covered injury.* A requester seeking payment or reimbursement for medical services or items already provided for a

covered injury or its health complications must submit an itemized statement from each healthcare provider or entity (*e.g.*, clinic, hospital, doctor, or pharmacy) and third-party payer 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 payer has an obligation to pay for or provide such services or items, the requester must so certify in writing 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 to diagnose, treat, or prevent its health complications, the requester may submit, in addition to the required medical records, documentation showing that a health-care provider prescribed or recommended such services or items. The medical records must support the requested services and items.

(3) *Documents for medical services and items expected to be provided in the future.* A requester seeking payments for medical services or items resulting from a covered injury or its health complications expected to be provided in the future must submit a statement from each healthcare provider (*e.g.*, a treating neurologist for neurological issues and a treating cardiologist for cardiac issues) describing those services and items that appear likely to be needed to diagnose or treat the covered injury, or to diagnose, treat, or prevent 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 covered by third-party payers for, such services or items. Consent for the Program to communicate directly with the healthcare providers may also be required.

§ 110.61 Documentation a requester who is determined to be eligible must submit for the

Secretary to make a determination of lost employment income benefits.

(a) A requester determined by the Secretary to be eligible for Program benefits and who seeks benefits for lost employment income must provide, in addition to the documentation submitted under Subpart F of this part, documentation describing:

(1) The number of days (including partial days) of work missed by the injured countermeasure recipient as a result of the covered injury or its health complications for which employment income was lost (*e.g.*, time sheet from the relevant pay period(s) showing work days missed). As stated in § 110.32(c), days for which an individual used paid leave will be considered days of work for which employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days; and

(2) The injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return or pay stub(s) from all employers at the time of the covered injury); and

(3) Whether the injured countermeasure recipient had one or more dependents at the time the covered injury was sustained (*e.g.*, the individual's Federal tax return at the time of the covered injury); and

(4) A list of all third-party payers that have paid, or that may be obligated to pay, benefits to the injured countermeasure recipient for loss of employment income or provide disability and/or retirement benefits for which payment or reimbursement is being sought under this Program (*e.g.*, State workers' compensation programs, disability insurance programs, Uniform Services Retirement Board determinations, Department of Veterans Affairs determinations, etc.). A requester must

submit documentation, if available, concerning the amount of such payments or benefits paid or payable to, or on behalf of, the injured countermeasure recipient by third-party payers. If the requester knows of no such third-party payer, he or she must so certify in writing. If, at any time, the requester becomes aware that a third-party payer may have such an obligation, the requester must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

§ 110.62 Documentation a requester who is determined to be an eligible survivor must submit for the Secretary to make a determination of death benefits.

(a) A requester determined by the Secretary to be an eligible survivor and who seeks a death benefit under § 110.82(b) (the standard calculation) must provide, in addition to the documentation submitted under Subpart F of this part, a written certification informing the Secretary whether a disability or death benefit was paid or payable under the PSOB Program with respect to the deceased injured countermeasure recipient. If such benefit was provided, the requester must submit documentation showing the amount of the benefit paid by the PSOB Program. If the deceased injured countermeasure recipient was covered under the PSOB and no such benefit was, or will be provided, the certification must explain whether any survivors are eligible for a death benefit under the PSOB Program and, if so, whether a death benefit may be paid or payable under the PSOB Program.

(b) The legal guardian seeking a death benefit under § 110.82(c) (the alternative calculation) on behalf of a dependent younger than the age of 18 determined by the Secretary to be an eligible survivor must provide, in addition to the documentation submitted under Subpart F of this part, the following:

(1) Documentation showing that the deceased injured countermeasure recipient 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); and

(2) 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 § 110.63(a). If multiple dependents have different legal guardians, the legal guardian of each of the dependents must submit such documentation; and

(3) 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 §110.82(c), in place of proportional benefits available under the standard calculation as described in § 110.82(b). Written selections are described in §110.82(c)(1); and

(4) Documentation showing the deceased injured countermeasure recipient's gross employment income at the time the covered injury was sustained (*e.g.*, the decedent's Federal tax return or pay stub(s) from all employers at the time of the covered injury); and

(5) A description of all third-party payers that have paid for, or that may be required to pay for, the benefits described in § 110.82(c)(3)(A). This description must include the amount of such benefits that have been paid or that may be paid in the future. If the representative knows of no such third-party payer, he or she must so certify in writing. If, at any time, the representative becomes aware that a third-party payer may have such an obligation, he or she must inform the Secretary within ten business days of becoming aware of this information, even after benefits have been paid by the Program.

§ 110.63 Documentation a legal or personal representative must submit when filing on behalf of a minor or on behalf of an adult who lacks legal capacity to receive payment of benefits.

Before benefits will be paid by the Program to an eligible requester who is a minor or an adult who lacks legal capacity to receive payment of benefits, his or her legal or personal representative must

submit the following, in addition to the documentation required under Subpart F of this part and, as applicable, §§ 110.60-110.62:

(a) *For an eligible requester who is a minor:*

(1) Documentation showing that the requester is a minor (*e.g.*, birth certificate); and

(2) Documentation showing that the representative is the legal guardian of the property or estate of the minor (*e.g.*, appointment of guardianship by a court of competent jurisdiction). If a minor has more than one legal guardian, this documentation is required only of one legal guardian. In the alternative, documentation showing that the minor is considered emancipated under applicable State law. In accordance with § 110.83(b), the Program reserves the right to waive the requirement of documentation of guardianship for good cause.

(b) *For an eligible requester who is an adult who lacks legal capacity to receive payment of benefits:*

(1) Documentation showing that the requester is an adult who lacks this legal capacity (*e.g.*, declaration of legal incapacity issued by a court of competent jurisdiction, or comparable documentation); and

(2) A decree by a court of competent jurisdiction establishing a guardianship or conservatorship of the requester's estate under applicable State law, or durable power of attorney, if applicable. In accordance with § 110.83(b), the Program reserves the right to waive this requirement for good cause.

Subpart H--Secretarial Determinations

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

Before the Secretary will pay benefits under this Program, she must determine that:

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

(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.

§ 110.71 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 so 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 provide a written explanation of the reason(s) that the requested documentation is unavailable and the efforts the requester has made to obtain the documents. The Secretary may accept such a statement in place of the required documentation or disapprove the Request for Benefits due to insufficient documentation. If insufficient documentation is submitted in response to the Secretary's letter, the Secretary may disapprove the Request for Benefits.

§ 110.72 Sufficient documentation for eligibility and benefits determinations.

(a) *Eligibility determinations.* When the Secretary determines that there is sufficient documentation in the Request Package to evaluate a requester's eligibility, she will begin the review to determine whether the requester is eligible for Program benefits. 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 right to reconsideration of the determination, as described in Subpart J.

(b) *Benefits determinations.* If the Secretary determines that the requester is eligible for benefits, she will, after receiving adequate 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 health insurance company, if none was submitted). As provided in Subpart J, requesters have the right to reconsideration of the Secretary's determination of the category and amount of benefits payable under the Program.

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

§ 110.73 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, she will so notify the requester (or his or her representative) in writing.

The Secretary will make payments in accordance with §110.83.

Once all benefits have been paid, the Request Package can no longer be amended (except for survivor benefits). The payment determination will constitute final agency action with regard to the particular countermeasure injury that is the subject of the Request for Benefits and payment (*i.e.*, the Request for Benefits is closed with regard to the injury that is the basis of the payment of benefits).

§ 110.74 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 for Benefits and provide the requester, or his or her representative, with written notice of the basis for the disapproval, and the right to reconsideration of the determination, as provided in §110.90.

(b) The Secretary may disapprove a Request for Benefits even before the requester has submitted all the required documentation (*e.g.*, the Secretary may determine that a requester did not meet the filing deadline, or that a covered countermeasure was not used or administered).

(c) The Secretary may re-open a disapproved Request for Benefits on her own accord should medical or scientific evidence later become available to justify a re-determination of the disapproval of eligibility or payments. In extraordinary circumstances, to be determined at the Secretary's discretion, she may re-open a disapproved Request for Benefits even after the requester has exercised the right to reconsideration and the disapproval determination has been upheld in accordance with the procedures set out in §110.90.

Subpart I--Calculation and Payment of Benefits

§ 110.80 Calculation of medical benefits.

In calculating medical benefits, the Secretary will take into consideration all reasonable costs for reasonable and necessary medical items and services to diagnose or treat a countermeasure recipient's covered injury, or to diagnose, treat, or prevent its health complications, as described in § 110.31. 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 § 110.60. The Secretary will make such payments only to the extent that such costs were not, and will not be, paid by any third-party payer and only if no third-party payer had or has an obligation to pay for or provide such services or items to the requester, except as provided in § 110.83(c) and § 110.84. There are no caps on the benefits for reasonable and necessary medical expenses that may be provided under the Program.

§ 110.81 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 injured countermeasure recipient lost employment income for the lost work days as reasonable based on the degree of injury or disability. As stated in § 110.32(c), days for which an individual used paid leave will be considered days of work for which

employment income was received and, therefore, would not qualify for lost employment income benefits. However, if the injured countermeasure recipient reimburses the employer for the paid leave taken and the employer restores the leave that was used, the individual may be eligible for lost employment income benefits for those days;

(1) The Secretary will calculate the rate of benefits to be paid for the lost work days based on the injured countermeasure recipient'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 an injured countermeasure recipient with no dependents at the time the covered injury was sustained, the benefits are 66 $\frac{2}{3}$ percent of the individual's gross employment income at the time of injury.

(B) For an injured countermeasure recipient with one or more dependents at the time the covered injury was sustained, the benefits are 75 percent of the individual's gross employment income at the time of injury; and

(C) In the case of an injured countermeasure recipient who is a minor, the Secretary may consider the provisions of 5 U.S.C. 8113 (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) *Number of lost work days.* An injured countermeasure recipient 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 five days. If the injured countermeasure recipient lost employment income for a period of five 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 the number of work days (or partial work days) lost as a result of a covered injury or its health complications in this calculation, and to consider alternative work schedules in determining the number of work days lost.

(2) *Annual limitation.* The maximum amount that an injured countermeasure recipient may receive in any one year in benefits for lost employment income under this Program is \$50,000.

(3) *Lifetime limitation.* The maximum amount that an injured countermeasure recipient 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 § 110.82(b). However, this lifetime cap does not apply if the Secretary determines that the countermeasure recipient 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).

(4) *Termination of payments.* The Secretary will not pay benefits for lost employment income after the injured countermeasure recipient reaches the age of 65.

(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 injured countermeasure recipient for compensation of lost employment income or disability or retirement benefits, by any third-party payer in relation to the covered injury or its health complications, consistent with § 110.32(b); and

(2) So that the total amount of benefits for lost employment income paid to an injured countermeasure recipient under this Program, together with the total amounts paid (or payable) by third-party payers, as described in paragraph (d)(1) of this section, does not exceed 66 $\frac{2}{3}$ percent (or 75 percent, if the injured countermeasure recipient 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.

(3) If an injured countermeasure recipient receives a lump-sum payment from any third-party payer under any obligation described in paragraph (d)(1) of this section, the Secretary shall consider 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.

§ 110.82 Calculation of death benefits.

(a) *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 (c)(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 § 110.33(b) and paragraph (b) of this section.

(2) If the Secretary approves a written selection to receive benefits under the alternative calculation, as described in paragraph (c)(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 countermeasure recipient is survived by a dependent ten year-old child and a spouse who is not the child's legal guardian (*e.g.*, the dependent child's parents were the deceased injured countermeasure recipient and his or her former spouse), the current 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 and the Secretary approved the selection).

(b) *Standard calculation of death benefits.*

(1) The maximum death benefit available under the standard calculation of death benefits (described in this paragraph) is the amount of the comparable death benefit calculated under the PSOB Program

in the same fiscal year in which the injured countermeasure recipient died (regardless of whether the PSOB Program reduces the amount of its death benefits because of a limit in appropriations).

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

(3) The death benefit will not be reduced under the standard calculation if a total and permanent disability benefit has been, or will be paid under the PSOB Program with respect to the deceased injured countermeasure recipient. However, the death benefit will be reduced if a temporary and partial disability benefit has been, or will be paid under the PSOB Program with respect to that individual. 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 (b)(1) of this section.

(4) Under the standard calculation, death benefits will be paid in a lump sum.

(c) *Alternative calculation of death benefits available to surviving dependents younger than the age of 18.* If a deceased countermeasure recipient 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(c)(1) of this section, and the Secretary must approve such selection. 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 the 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 percent of the deceased injured countermeasure recipient'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, 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 (described in this paragraph) will be reduced so that the total amount of payments made (or expected to be made) under obligations described in paragraph (c)(3)(i) of this section, together with the death benefits paid under the alternative calculation, is not greater than the amount of

payments described in paragraph (c)(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 payers have paid (or are expected to pay) for certain benefits so that such dependents will receive a total sum (combining the death benefit under the alternative calculation and the actual and expected benefits covered by third-party payers) that is not greater than the death benefit that would be available under the alternative calculation if there were no third-party payer(s) to pay such benefits. The total amount of death benefits will *not* be reduced by lost employment income paid by the Program.

(i) 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 payer for:

(A) Compensation for the deceased countermeasure recipient's loss of employment income on behalf of the dependents or their legal guardians(s) (but *not* any lost employment income benefits paid by the Program);

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

(C) Life insurance benefits on behalf of the dependents;

(4) *Timing of payments.* Payments made under this paragraph will be made on an annual basis, beginning from 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.

§ 110.83 Payment of all benefits.

(a) The Secretary determines the mechanism of payment of Program benefits. She may choose to 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 § 110.82(c)) will be required for a period in excess of one year from the date the Secretary determines the requester is eligible for such benefits, payments may be made through a lump-sum payment, the purchase of an annuity or medical insurance policy, establishment of a trust (including a U.S. grantor reversionary trust) or execution of an appropriate structured settlement agreement, at the Secretary's discretion. Payments, annuities, policies, or agreements must be 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 §§ 110.80, 110.81, and 110.82. Lump sum payments will be made through an electronic funds transfer to an account of the requester.

(b) If the requester is a minor, the payment will be made on the minor's behalf to the account of the legal guardian of the estate or property of the minor. In accepting such payments, the legal guardian of a minor requester is obligated 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 an adult who lacks the legal capacity to receive payment(s), 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. Documentation of guardianship (or conservatorship) is

required for requesters who are minors or adults who lack legal capacity unless the Secretary waives this requirement for good cause.

(c) The Secretary has the discretion to make interim payments of benefits under this Program, even before a final determination as to the type(s) and total amount of benefits that will be paid. Interim payments will be made only in exceptional cases. 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 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 countermeasure-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 Secretary. The requester must agree that he or she will be obligated to repay the Secretary such benefits in the event that a Program payment is later determined to be incorrect. 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 final benefits determination.

§ 110.84 The Secretary's right to recover benefits paid under this Program from third-party payers.

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 payer with a legal or contractual obligation to pay for (or provide) such benefits and may recover from such third-party payer(s) the amount of benefits paid up to the amount of benefits the third-party payer 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 payer in certain circumstances. In those circumstances, the Secretary has a right to be reimbursed by the third-party payer. 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 payer 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 payer after receiving the same type of benefits from the Secretary under this Program, the Secretary has a right to recover from the requester the amount of the benefit(s) received. The requester must notify and reimburse the Program within ten business days of receiving the third-party payment(s).

Subpart J--Reconsideration of the Secretary's Determinations

§ 110.90 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 Program benefits. In addition, a requester who asserts that the amount of the benefits paid (or the fact that certain benefits were not paid or payable) is incorrect may also seek reconsideration. A requester may not seek reconsideration of the Secretary's decision as to the mechanism of payment. Requests for 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 for Benefits. Because no new documentation will be considered in the reconsideration process, the reconsideration request may not include or refer to any documentation that was not before the Secretary at the time of her determination.

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

letters seeking reconsideration are not currently accepted, but may be accepted in the future. The Program will publish a notice if an electronic method becomes available. Letters sent through the U.S. Postal Service, commercial carrier or private courier service must be sent to the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12-105, Rockville, Maryland 20857.

(c) *Reconsideration process.* When the Associate Administrator of the Healthcare Systems Bureau (the Associate Administrator), receives a request for reconsideration, a qualified panel, independent of the Program, will be convened to review the Secretary's determination. The panel will base its recommendation on the documentation before the Secretary when the determination 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 request for reconsideration and will be considered the Secretary's final determination on the request for Program benefits with regard to the injury that is the subject of that Request Package. Requesters may not seek review of a decision made on reconsideration.

(d) *Effect of reconsideration on amending a Request Package.* As stated in §110.46, a Request Package cannot be amended after exhaustion of the reconsideration process, except for amendments by survivors seeking death benefits or executors or administrators on behalf of an estate

§ 110.91 Secretary's review authority.

Under section 319F-4(b)(4) of the Public Health Service Act (42 U.S.C. 247d-6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), the Secretary may, at any time, on her own motion or on application, review any determination made under this part (including, but not limited to, determinations concerning eligibility, entitlement to benefits, and the calculation of amount of benefits under the

Program). Upon review, the Secretary may affirm, vacate, or modify the determination in any manner the Secretary deems appropriate.

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

(a) Under section 319F-4(b)(4) of the PHS Act (42 U.S.C. 247d-6e(b)(4)) (referencing section 262 of the PHS Act (42 U.S.C. 239a)), no judicial review of the Secretary's actions concerning eligibility and benefits determinations under this part (including, but not limited to, determinations concerning eligibility, the type or amount of benefits, and the method of payment of benefits) is permitted. In addition, no further administrative review of such actions are permitted unless the President specifically directs otherwise.

(b) Under section 319F-4(b)(5)(c) of the PHS Act (42 U.S.C. 247d-6e(b)(5)(c)), no judicial review of the Secretary's actions in establishing or amending a Table (or Tables) for purposes of this part (which include, but are not limited to, identifying injuries on a Table (or choosing not to identify injuries on a Table), establishing time-frames or definitions for Table injuries, and amending a Table) is permitted.

Subpart K—Covered Countermeasures Injury Tables

[Reserved]