



Overview of Health Resources and Services Administration (HRSA)'s Injury Compensation Programs

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Vision: Healthy Communities, Healthy People



Outline of Presentation

- Overview of the National Childhood Vaccine Injury Act and the National Vaccine Injury Compensation Program (VICP)
- Overview of the Public Readiness and Emergency Preparedness Act (PREP Act) and the Countermeasures Injury Compensation Program (CICP)



VICP and the National Childhood Vaccine Injury Act

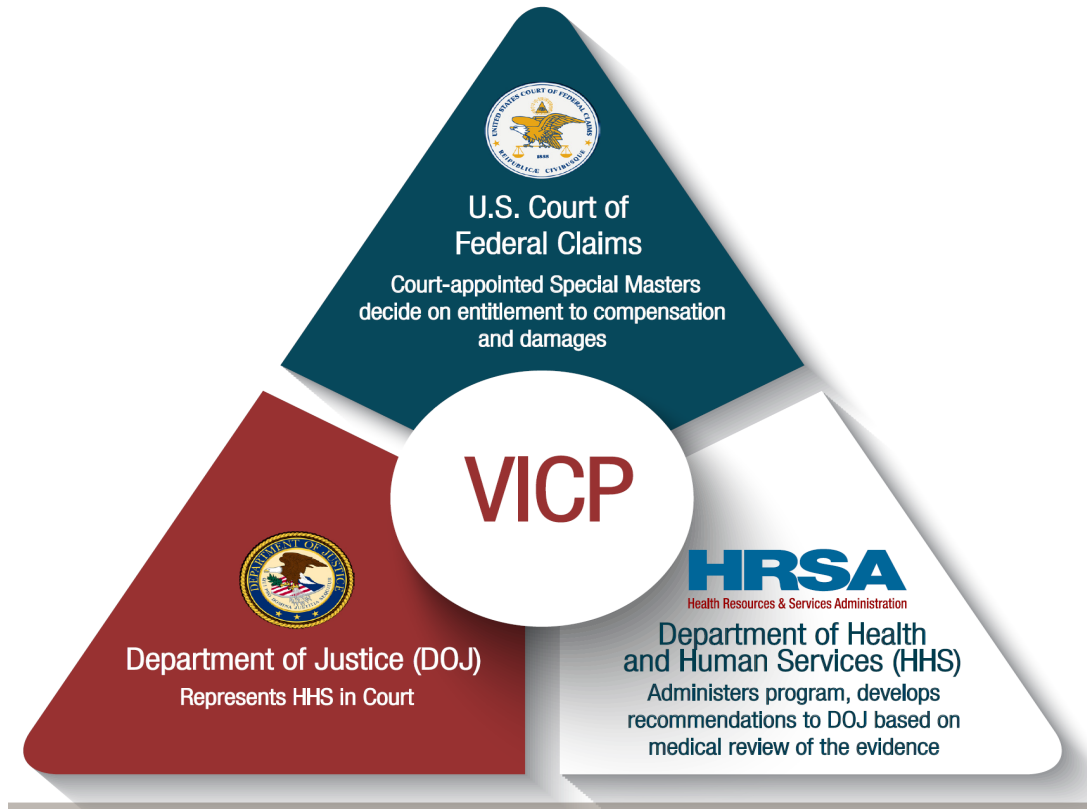


National Childhood Vaccine Injury Act of 1986

- The VICP was established in 1988
- Purpose of the VICP
 - To ensure that individuals injured by certain vaccines are provided with fair and efficient compensation
 - To ensure a stable vaccine supply by limiting liability for vaccine manufacturers and vaccine administrators
 - ✓ Claims generally must first be filed with VICP before seeking civil remedies

THE NATIONAL VACCINE INJURY COMPENSATION PROGRAM (VICP)

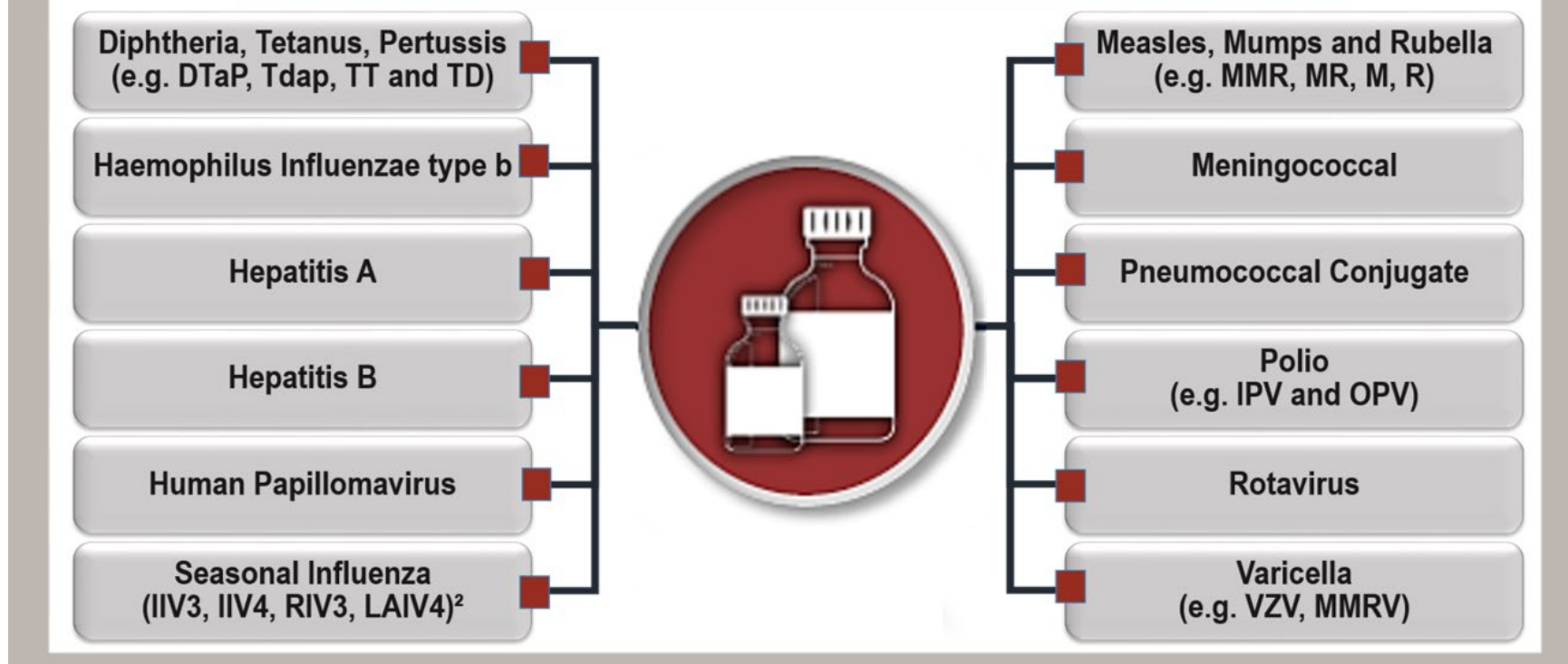
VICP ROLES



Who May File a Petition?

- Anyone who received a vaccine covered by the VICP and is thought to be injured by the vaccine
- Parent or legal guardian of a child or disabled adult or legal representative of the estate of the deceased person who received a vaccine

COVERED VACCINES¹



¹ Recommended by CDC for routine use in children and/or in pregnant women and subject to an excise tax

² Seasonal (trivalent, quadrivalent, inactivated, live attenuated and recombinant vaccines) only

Vaccine Injury Table

Applies Only to Petitions for Compensation Filed under the National Vaccine Injury Compensation Program on or after January 3, 2022

(a) In accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Public Law 99-660, 100 Stat. 3779 ([42 U.S.C. 300aa-1](#) note) and section 2114(c) of the Public Health Service Act, as amended (PHS Act) ([42 U.S.C. 300aa-14\(c\)](#)), the following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program. [Paragraph \(b\)](#) of this section sets forth additional provisions that are not separately listed in this Table but that constitute part of it. [Paragraph \(c\)](#) of this section sets forth the qualifications and aids to interpretation for the terms used in the Table. Conditions and injuries that do not meet the terms of the qualifications and aids to interpretation are not within the Table. [Paragraph \(d\)](#) of this section sets forth a glossary of terms used in paragraph (c).

Vaccine	Illness, disability, injury or condition covered	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration
I. Vaccines containing tetanus toxoid (e.g., DTaP, DTP, DT, Td, or TT)	A. Anaphylaxis	≤4 hours.
	B. Brachial Neuritis	2-28 days (not less than 2 days and not more than 28 days).
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.
II. Vaccines containing whole cell pertussis bacteria, extracted or partial cell pertussis bacteria, or specific pertussis antigen(s) (e.g., DTP, DTaP, P, DTP-Hib)	A. Anaphylaxis	≤4 hours.
	B. Encephalopathy or encephalitis	≤72 hours.
	C. Shoulder Injury Related to Vaccine Administration	≤48 hours.
	D. Vasovagal syncope	≤1 hour.

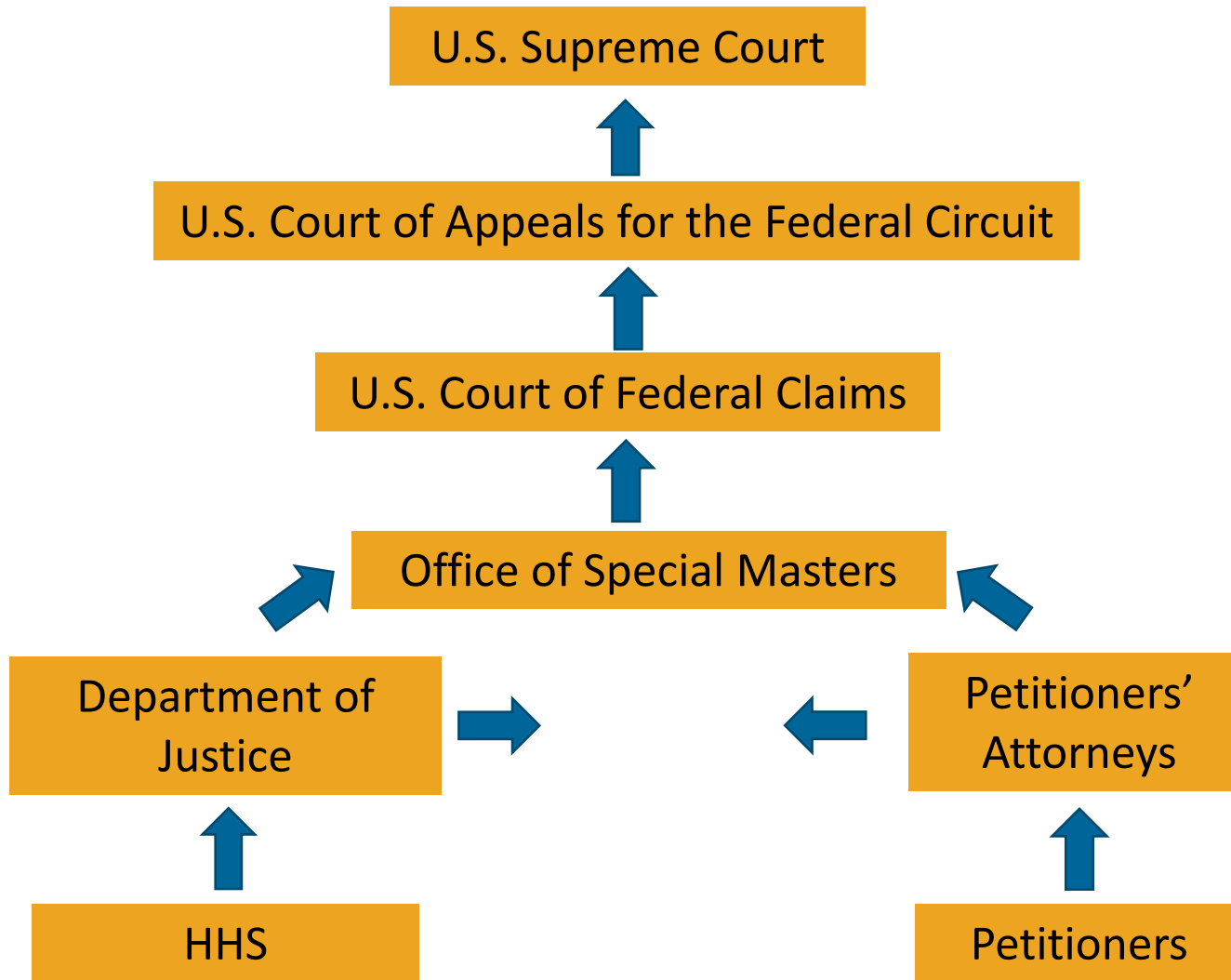


Claims Process

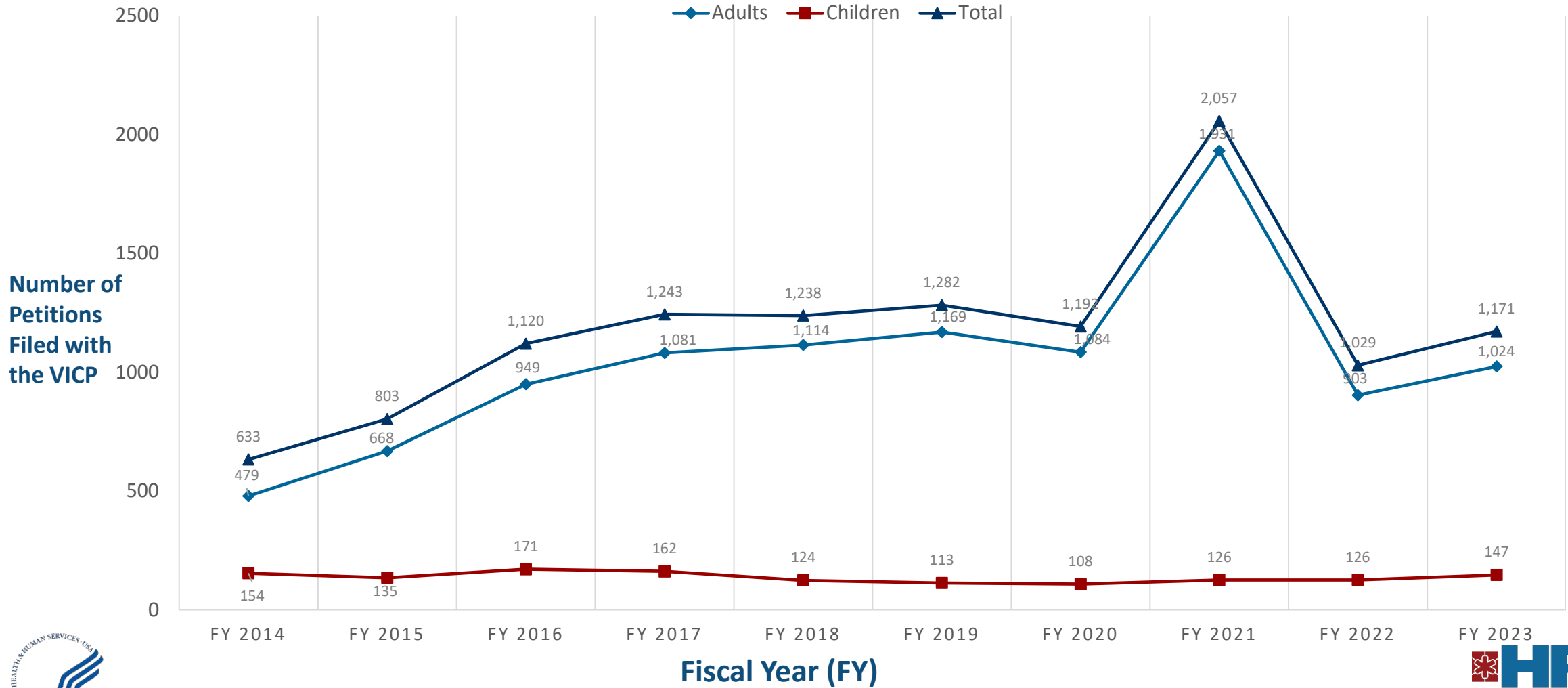
1. Petitioner files a claim and supporting documents with the U.S. Court of Federal Claims (Court) and the Department of Health and Human Services (HHS)
2. HHS reviews and sends recommendations to the Department of Justice (DOJ)
3. DOJ conveys the HHS Secretary's position to the Court
4. Court issues final decision



VICP Adjudication Process



VICP Petitions Filed for Adults and Children FY 2014 – FY 2023



Criteria for Compensation

- To be compensated, one must demonstrate one of the following:
 - proof of an injury on Vaccine Injury Table
 - proof of causation
 - proof of significant aggravation
 - ✓ unless alternative cause unrelated to vaccine is found
- Standard of proof (civil standard)
 - Preponderance of evidence (more likely than not)
- Effects of injury must:
 - last greater than 6 months, or
 - have resulted in inpatient hospitalization AND surgical intervention, or
 - death



VICP Benefits

- The VICP is the payer of last resort, with the exception of Medicaid
- Types of payments include:
 - Reasonable unreimbursed medical expenses
 - Lost earnings
 - Pain and suffering (up to \$250,000)
 - Attorney's fees and costs
 - Death benefit (up to \$250,000)



CICP and the PREP Act



PREP Act Overview

- Authorizes the Secretary of HHS to issue PREP Act Declarations
- Declarations provide immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency



PREP Act Liability Protections

- In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration
 - The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct

PREP Act Compensation Requirements

- Allows for compensation for serious physical injuries or deaths directly caused by the administration/use of countermeasures covered by declarations.
 - Authorized a Covered Countermeasures Process Fund (i.e., CICP)
- If one of the following occurs, then an individual may pursue a tort claim in the United States District Court for the District of Columbia, but only if the claim involves willful misconduct and meets the other requirements for suit under the PREP Act:
 - ✓ funding has not been appropriated for the program;
 - ✓ the program fails to make a final determination within 240 days after a request was filed; or
 - ✓ the program determines that a covered individual qualifies for compensation, but the individual decides not to accept the compensation



CICP Compensation Requirements

- Provides compensation to eligible individuals who sustain a serious injury or death directly caused from administration/use of covered countermeasure
 - Based on *“compelling, reliable, valid, medical and scientific evidence”*
- Serious injuries are defined as those
 - warranting hospitalization (whether the individual was hospitalized or not), or
 - leading to a significant loss of function or disability.
- Requests for benefits (RFB) must be filed within 1 year of administration/use of covered countermeasure



CICP Covered Threats

- PREP Act Declarations have been issued for medical countermeasures against the following threats:
 - COVID-19
 - Marburg
 - Ebola
 - Nerve Agents and Certain Insecticides (Organophosphorus and/or Carbamates)
 - Zika
 - Pandemic Influenza
 - Anthrax
 - Acute Radiation Syndrome
 - Botulinum Toxin
 - Smallpox and other orthopoxviruses



CICP Eligible Requesters

- Injured countermeasure recipients
- Legal or personal representative on behalf of an injured countermeasure recipient
- Survivors of deceased injured countermeasure recipient
- Estates of deceased injured countermeasure recipient



Summary of the CICP Process

1. An individual submits an RFB Package.
2. Once all expected medical records are received, the case is put in queue for review
3. The Package is reviewed by CICP medical staff to determine whether the requester is eligible for program benefits, including whether a covered injury was sustained.
4. If the requester is determined to be eligible for program benefits, the requester is asked to submit additional documentation to determine the type and amount of compensation the requester may be entitled to receive.
5. The requester is notified in writing either if they were found entitled to program benefits, or if they were found ineligible for benefits.



Summary of the CICP Process (continued)

5. The requester may ask for reconsideration of the program's determination. When a request for reconsideration is received, a qualified panel, independent of the program, is convened to review the program's determination.
6. The panel makes its recommendation to the Health Systems Bureau's Associate Administrator, who makes a final determination. Requesters may not seek review of a decision made on reconsideration.



CICP Data as of September 1, 2023

- Total CICP Claims Filed: **12,775**
 - Total COVID Claims: **12,233**
- Decisions: **1,728** (**1,267** COVID-19 decisions rendered)
 - Eligible for Compensation: **72**
 - ✓ Compensated: **36**
 - ✓ Pending Benefits Determination: **25**
 - ✓ No Eligible Reported Expenses: **11**
 - Pending Review or In Review: **10,975**
 - Denied: **1,728**
 - ✓ Requested Medical Records not Submitted: **182**
 - ✓ Standard of Proof Not Met and/or Covered Injury not Sustained: **437**
 - ✓ Missed Filing Deadline: **765**
 - ✓ Not CICP Covered Product/Not Specified: **344**



CICP Benefits

- The CICP is the payer of last resort, which means that it covers what remains unpaid or unpayable by other third parties
- Types of CICP benefits include:
 - Reasonable Unreimbursed Medical Expenses
 - Lost Employment Income
 - Death Benefit



Questions?



Contact Information

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CICP Web: <https://www.hrsa.gov/cicp>



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