



Overview of the Countermeasures Injury Compensation Program (CICP)

133rd ACCV Meeting

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CAPT Reed Grimes, MD, MPH
Director, Division of Injury Compensation Programs
Health Systems Bureau (HSB)

Vision: Healthy Communities, Healthy People



Public Readiness and Emergency Preparedness Act (PREP Act)

- Public Readiness and Emergency Preparedness Act (PREP Act)
 - Signed into law by President George W. Bush in December 2005
 - Authorizes the Secretary of Health and Human Services (HHS) to issue PREP Act Declarations
 - Established the Covered Countermeasures Process Fund
 - Created targeted liability protections for persons or entities involved in emergency response efforts covered by PREP Act Declarations



PREP Act

Present/Credible Risk of Future Public Health Emergency
from Pandemic, Bioterrorism or Security Threat

PREP Act Declarations

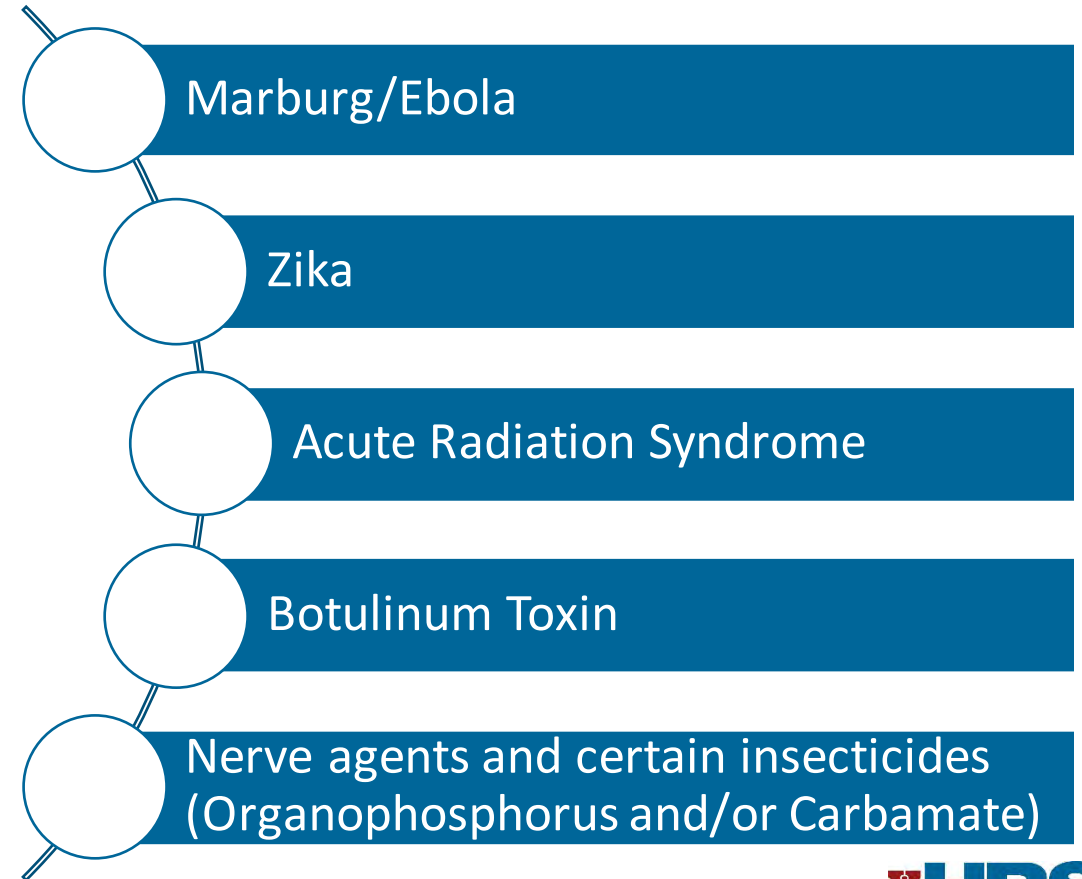
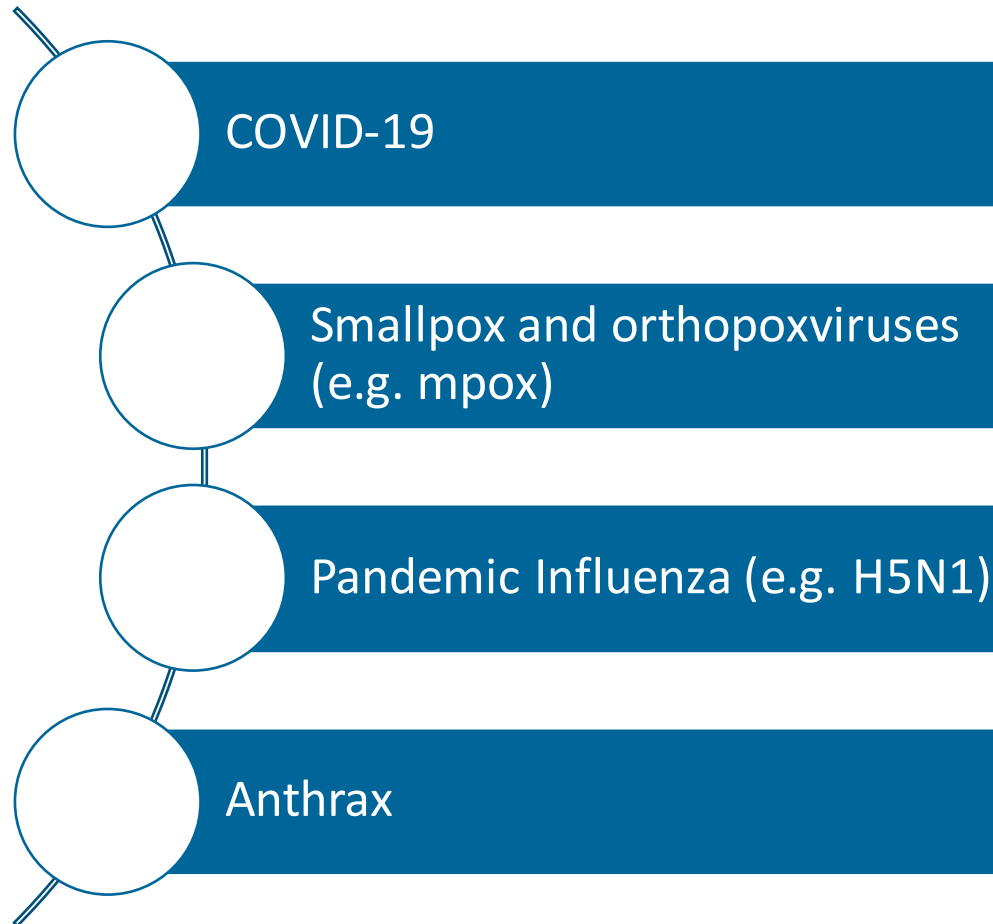
Liability Immunity

Countermeasures Injury Compensation Program



PREP Act Declarations

PREP Act Declarations have been issued for medical countermeasures against the following:



Countermeasures Injury Compensation Program (CICP)

Purpose

The purpose of CICP is to provide compensation for covered serious injuries or death that occur as the direct result of the administration or use of certain covered countermeasures.

The CICP establishes and maintains an accessible forum for timely, uniform, and adequate compensation for individuals for covered injuries directly caused by the administration or use of covered countermeasures.



Covered Countermeasures

- A drug, biological product, or device used to prevent, diagnose, mitigate, treat, or cure a pandemic or epidemic or limit the harm such pandemic or epidemic might otherwise cause
- Covered countermeasures are identified in PREP Act Declarations
- A covered countermeasure must have been administered or used for an injured countermeasure recipient to be eligible for Program benefits
- Individuals who sustained an injury from the covered disease/threat (e.g., COVID-19) rather than a covered countermeasure are not eligible for benefits
 - Must have been injured by a covered countermeasure



Eligible Individuals

- Injured countermeasure recipients
- Survivors of the deceased injured countermeasure recipient
- Estates of the deceased injured countermeasure recipient
- Legal or personal representative (e.g., lawyer, guardian, family member, or friend) of the injured countermeasure recipient may file on behalf of a requester but are not eligible for benefits



Injuries Eligible for CICP Benefits (Covered Injuries)

- Covered injury means death, or a serious physical injury, determined by the Secretary to be:
 - 1) **Table Injury** – 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) **Non-table Injury** – 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. Proof must be based on **compelling, reliable, valid, medical and scientific evidence**. Temporal association between receipt of the countermeasure and onset of injury is not sufficient by itself to prove that the countermeasure caused the injury.



CICP Serious Injury Requirement

- Covered injuries must meet the CICP's statutory and regulatory serious injury requirement
- As a general matter, only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or led to a significant loss of function or disability are considered serious injuries
- 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.



Covered Countermeasures Injury Table Establishment

- Shall be established by the Secretary when the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of a covered countermeasure directly caused a covered injury
- An injury that meets the qualifications and time of onset on a Table is entitled to a presumption that the injury was caused by the specified covered countermeasure.
- To establish a Countermeasures Injury Table, HHS would:
 - Publish a notice of proposed rulemaking in the *Federal Register*
 - Provide a 60-day public comment period, and
 - Publish as a Final Rule



Covered Countermeasures Injury Table Updates

- Covered Countermeasures Injury Tables have been published for:
 - Smallpox Countermeasures (2021)
 - Pandemic Influenza Countermeasures (2015)
- National Academies of Sciences, Engineering, and Medicine (NASEM) recently reviewed evidence regarding 19 potential harms from each of the 4 COVID-19 vaccines
- Development of the COVID-19 Countermeasures Injury Table is currently underway as reflected in the Fall 2024 Unified Agenda



Types of payments authorized in CICP

- All benefits are secondary to any obligation of any third-party payer. Requesters may be eligible to receive the following benefits:
 - 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
 - 2) A portion of lost employment income incurred as a result of a covered injury
 - 3) Death benefits to certain survivors, if determined that death was the direct result of covered injury (amount based on Public Safety Officers' Benefit Program)
- By statute, neither damages for pain-and-suffering nor attorney's fees are payable

Requester Category	Medical	Lost Employment Income	Death
Injured Countermeasure Recipient	Yes	Yes	No
Survivors	No	No	Yes
Estates of deceased	Yes	Yes	No



CICP Processes



Procedures for Filing Request Packages

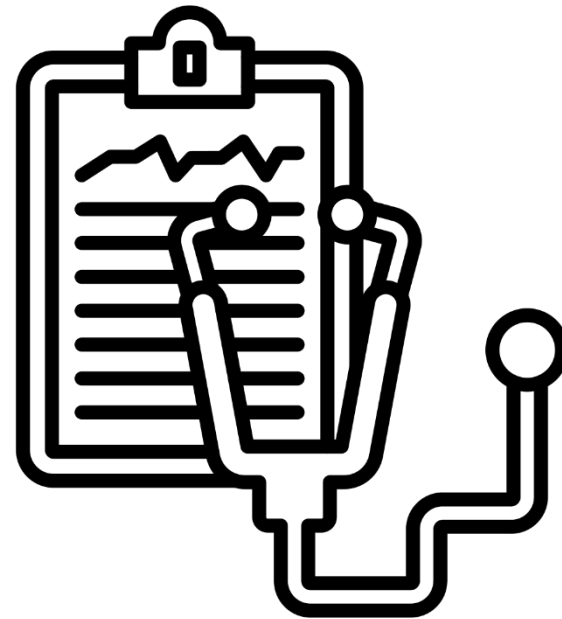
- Requests for Benefits (RFB) Forms (or Letters of Intent) need to be submitted by mail or online portal within one year of administration or use of the countermeasure that is alleged to have caused the injury.
- RFB Package includes:
 - RFB Form
 - Authorization for Use or Disclosure of Health Form for each medical provider that provided treatment and can show one year of pre-existing medical history
 - Medical Records
 - Proof of administration or use of a covered countermeasure (e.g., COVID -19 vaccine card)



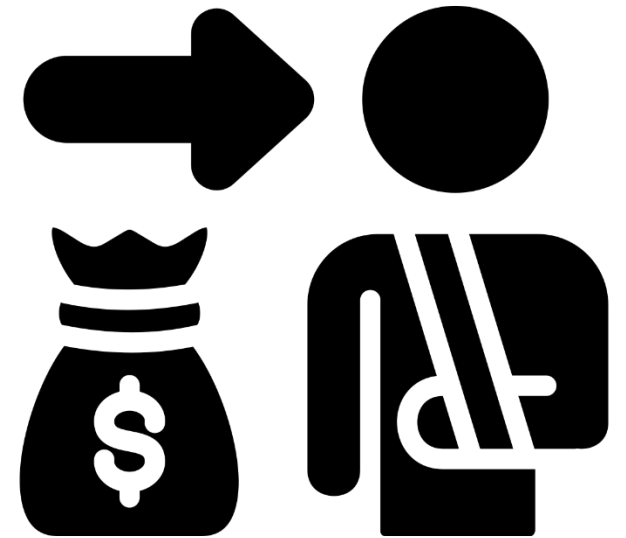
Review Process



Administrative (RFB) Review



Medical Eligibility Review



Benefits Determination

Review Process



Administrative (RFB) Review



Medical Eligibility Review

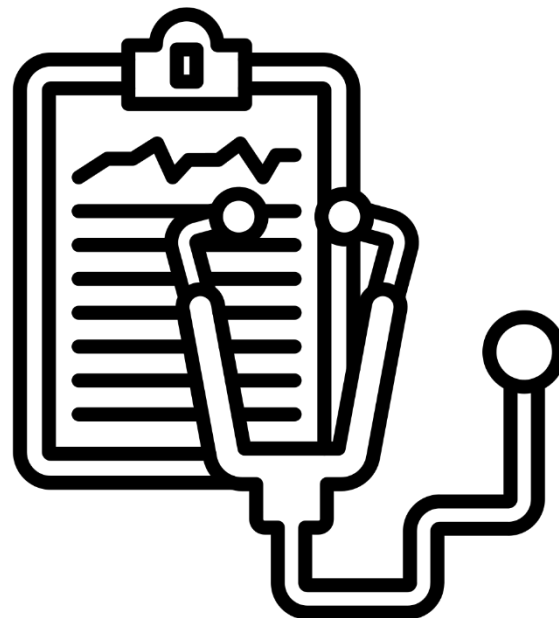


Benefits Determination

Review Process



Administrative (RFB) Review



Medical Eligibility Review



Benefits Determination

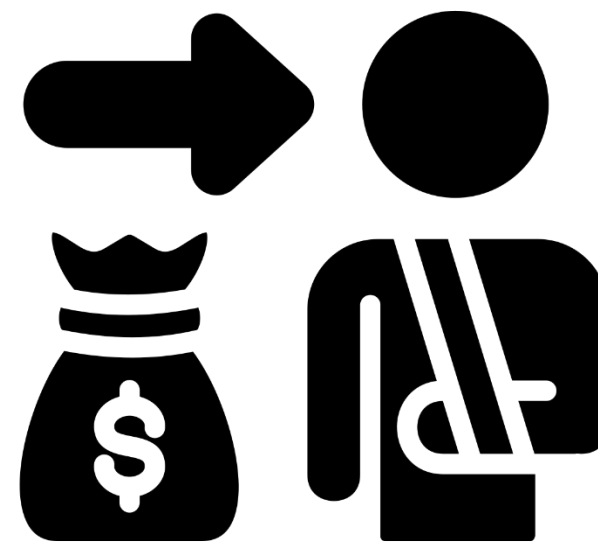
Review Process



Administrative (RFB) Review



Medical Eligibility Review



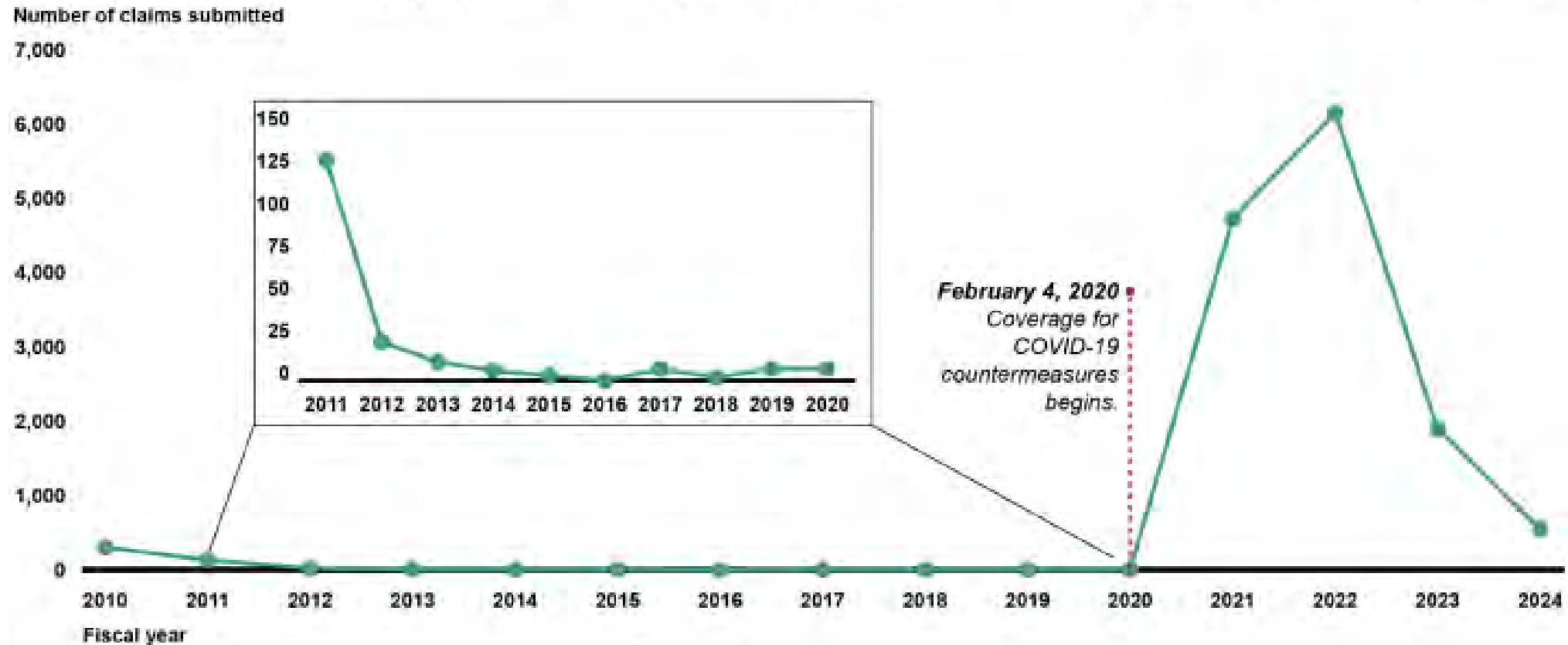
Benefits Determination

CICP Progress Updates



Number of CICP Total Claims, FY2010 – June 2024

Figure 2: Countermeasures Injury Compensation Program (CICP) Total Claim Submissions, by Fiscal Year, as of June 2024



Source: GAO analysis of Health Resources and Services Administration data. | GAO-25-107368

Notes: Data reflect October 2009, when the agency began accepting CICP claims, through June 2024, the most recent data available when we conducted our analysis. Fiscal year 2024 includes claims through June.



CICP Resources

- At the beginning of the COVID-19 pandemic, CICP had four (4) staff supporting CICP operations
- CICP had not received a direct appropriation since its inception in FY 2009
 - First direct appropriation (\$5 million) in FY 2022
 - Received subsequent direct appropriations of \$7M in FY 2023 and FY 2024
- Available funding has allowed CICP to increase staff and expedite claim review throughput



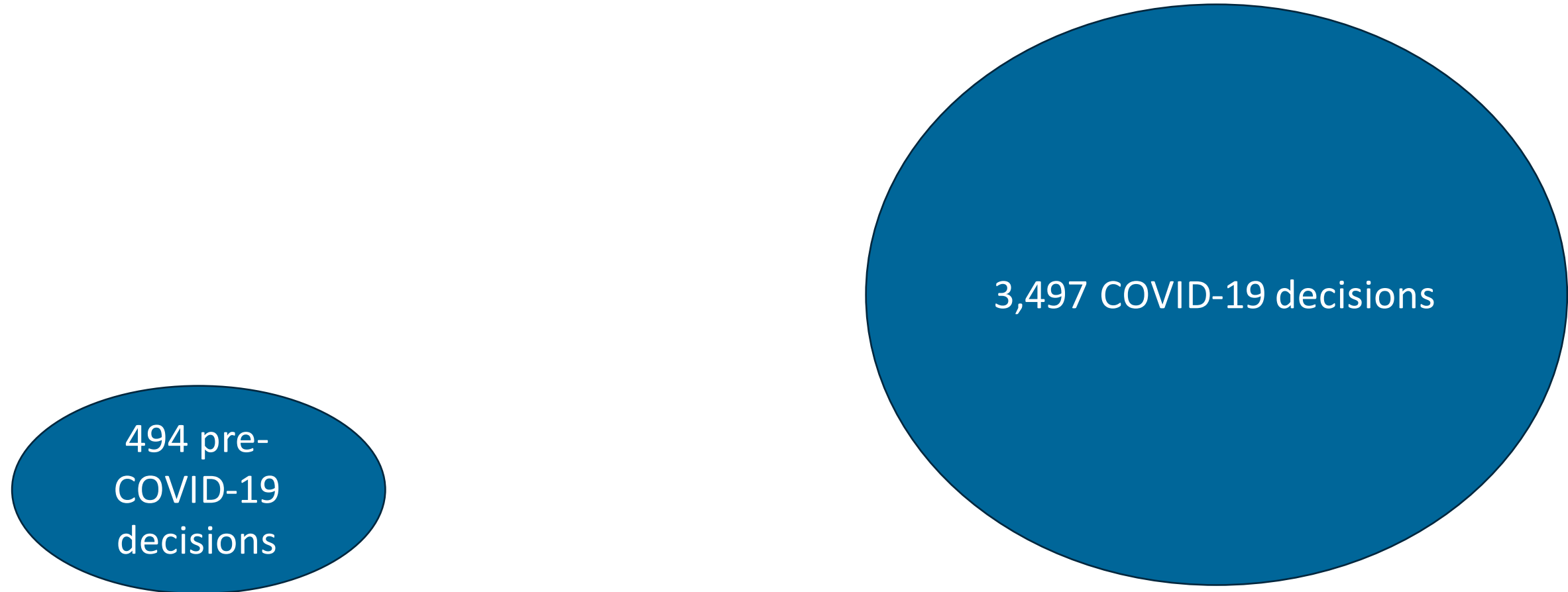
Number of CICP Program Decisions, pre-vs- post COVID-19 Declaration, FY 2010 – December 1, 2024

494 pre-
COVID-19
decisions

*CICP Data is updated monthly at <https://www.hrsa.gov/cicp/cicp-data>.

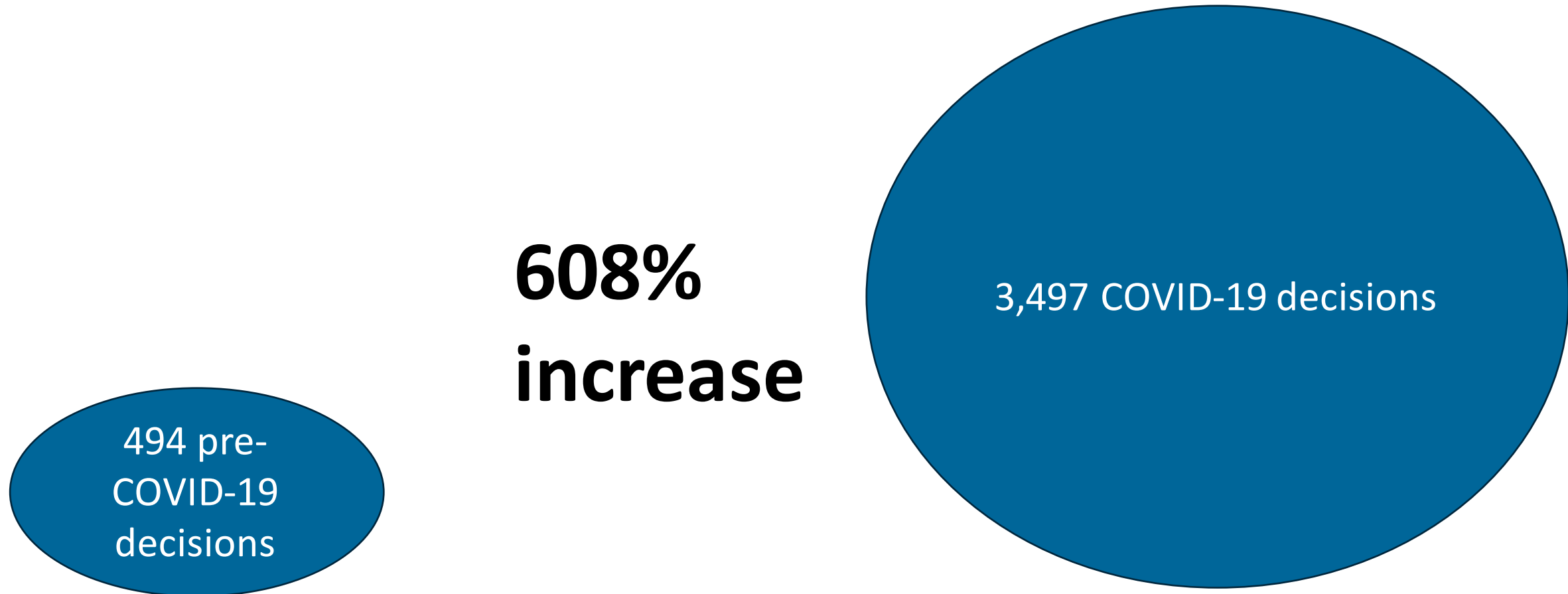


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Amount of Compensation by Covered Countermeasure, FY 2010 - Present

Covered Countermeasure	Compensation Amounts
2009 H1N1 Vaccine	\$5,755,053
Smallpox Vaccine	\$323,036
COVID-19 Vaccine	\$448,666
TOTAL	\$6,526,755



Comparison of CICP to VICP



Comparison of CICP vs. VICP

Program Categories	CICP	VICP
Program Authorization	Public Readiness and Emergency Preparedness Act (PREP Act) (42 U.S.C. §§ 247d-6d, 247d-6e)	National Childhood Vaccine Injury Act of 1986 , as amended (42 U.S.C. § 300aa-10, et seq.)
Filing Deadlines	<p><u>One (1) year filing deadline from the date of the administration or use of a covered countermeasure that is alleged to have caused the injury;</u> and, <u>One (1) year filing deadline from the effective date of the establishment of, or amendment to a countermeasures injury table</u></p>	<ul style="list-style-type: none"> • <u>Injury claim filing deadline within 3 years after the first symptom of the vaccine injury</u> • <u>Death claim filing deadline within 2 years of the death and 4 years after the start of the 1st symptom of the vaccine related injury from which death occurred</u> • <u>Filing deadline when changes are made to the Vaccine Injury Table within 2 years from the date the vaccine or injury/condition is added to the Table for injuries or deaths that occurred up to 8 years before the Table change.</u>



Comparison of CICP vs. VICP

Program Categories	CICP	VICP
Products Covered	Covered countermeasures are identified by the Secretary of the Department of Health and Human Services (HHS) in declarations published under the PREP Act. Covered Countermeasures	Vaccines recommended for routine administration to children and/or pregnant women by the Centers for Disease Control and Prevention, subject to a Federal excise tax, and added to the Vaccine Injury Table by the Secretary of HHS. Covered Vaccines
Process for Adding Covered Vaccines/ Countermeasures	Covered countermeasures are identified by the Secretary of HHS in declarations published under the PREP Act.	For a category of vaccines to be covered by the VICP, the category of vaccines must be recommended for routine administration to children and/or pregnant women by the Centers for Disease Control and Prevention, subject to an excise tax by federal law, and added to the Vaccine Injury Table by the Secretary of Health and Human Services.
Type of Injury Covered	Serious physical injuries Deaths	Injuries with residual effects lasting for more than 6 months after the vaccine was administered, or that resulted in inpatient hospitalization and surgical intervention, or Deaths from the administration of the vaccine.



Comparison of CICP vs. VICP

Program Categories	CICP	VICP
Process for Resolving Requests/ Petitions	Administrative Process	Judicial Process
Payment of Legal Fees and Costs	Attorneys' fees and costs are not paid by the program.	Attorneys' fees and costs may be available if certain requirements are met (petition filed in good faith and on a reasonable basis)
Covered Injury Determinations	HHS Secretary or her designee makes decision. Criteria to Demonstrate that a Covered Injury Occurred	Special Masters (or judges) of U.S. of Court of Federal Claims make decision. Criteria to be Found Eligible to Receive Compensation
Appeal Rights	Administrative reconsideration can be requested by requester.	Judicial appeal by either party.
Source of Program Funding	Annual Appropriations Emergency Supplemental Funding	Annual Appropriations from Vaccine Injury Compensation Trust Fund <ul style="list-style-type: none"> • Discretionary (administrative) • Mandatory (claims)



Summary

- The CICP was developed to be a forum for timely, uniform, and adequate fair compensation for serious physical injuries and/or deaths directly caused by the administration or use of from covered countermeasures
 - The PREP Act offers liability protections for covered entities and individuals
- Major uptick in claims filed since COVID-19
- Major uptick in decision throughput since increased resources allocated to CICP during COVID-19 pandemic
- CICP continues to work through substantial number of COVID-19 claims filed



Contact Information

CAPT Reed Grimes, MD, MPH
Director of Division of Injury Compensation Programs
5600 Fishers Lane, Room 08-25W
Rockville, Maryland 20857
Phone: 1-800-338-2382
Email: CICP@hrsa.gov
Web: hrsa.gov/about/organization/bureaus/hsb/
Twitter: twitter.com/HRSAgov
Facebook: facebook.com/HHS.HRSA



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