U.S. Government Accountability Office

COVID-19: Information on HHS's Medical Countermeasures Injury Compensation Program

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Q&A Report to Congressional Committees
December 18, 2024

Why This Matters

Medical countermeasures, such as vaccines and drugs, are developed to save lives during a public health emergency or security threat, such as the COVID-19 pandemic. Most people who receive a medical countermeasure have no serious problems, but like any medicine, there is a rare chance that a medical countermeasure can cause serious physical injuries or deaths. Individuals who die or are seriously injured by the administration or use of certain medical countermeasures may be eligible to receive compensation.

To encourage the development of countermeasures, the Public Readiness and Emergency Preparedness Act (PREP Act) limited the legal liability of manufacturers, distributors, health care providers, and others for losses related to the administration or use of covered countermeasures. It also authorized the Department of Health and Human Services (HHS) to establish the Countermeasures Injury Compensation Program (CICP), which began accepting claims in October 2009. Instead of suing manufacturers or others, individuals can apply to CICP for compensation for serious physical injuries or deaths resulting from covered countermeasures. CICP is operated by the Health Resources and Services Administration (HRSA)—an agency within HHS. Foreign countries also operate medical injury compensation programs.

The CARES Act includes a provision for us to report on the federal government's ongoing monitoring and oversight efforts related to the COVID-19 pandemic.[1] In this report we describe CICP, including its claims adjudication process, and similar programs in selected foreign countries.

Key Takeaways

- HRSA received a large influx of claims in response to the COVID-19 pandemic. Specifically, HRSA received approximately 27 times more claims in response to the COVID-19 pandemic than it had received in the entire first decade of the program—13,333 compared to 491 claims, respectively.
- Of the 13,824 total CICP claims received since the start of the program, HRSA had completed the adjudication process for 3,483 of them (25 percent), as of June 2024 (the most recent data available at the time of our analysis). The remaining 10,341 claims were under review or pending HRSA's review. Of the adjudicated claims, 3 percent (92) were found eligible to receive compensation for a serious injury or death directly caused by a covered countermeasure. Most of the claims eligible to receive compensation were for serious injuries or deaths caused by COVID-19 countermeasures (52) or for serious injuries caused by the H1N1 vaccine (37).
- Nearly all the challenges HRSA experienced operating CICP stem from the large influx of claims related to COVID-19 countermeasures and limited

resources prior to fiscal year 2022, according to HRSA officials. These challenges included having to handle the surge of claims with a shortage of staff and outdated information systems as well as having limited scientific evidence concerning whether injuries or deaths were directly caused by COVID-19 countermeasures. To address these challenges, HRSA hired more full-time staff and contractors and launched a web portal for online claims submissions.

- Thirty-eight foreign countries operate medical injury compensation programs, including nine developed during the COVID-19 pandemic, according to research. Additionally, there are three international medical injury compensation programs. These foreign programs primarily focus on harm from vaccines, and not from other drugs or medical devices.

Who is eligible to receive compensation under CICP for injuries or deaths caused by vaccines or other covered countermeasures?

There are three categories of individuals eligible to receive compensation through CICP, according to HRSA regulations: (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).[2] Compensation under CICP may include medical expenses, a portion of lost employment income, and a survivor death benefit.[3]

To be eligible for compensation, individuals must file a request for benefits form or letter of intent within one year of the administration or use of a covered countermeasure and provide medical documentation to support that a covered countermeasure directly caused a serious physical injury or death.[4] Generally, only injuries warranting hospitalization or those leading to a significant loss of function or disability are considered serious, according to HRSA regulations. For HRSA to determine the type and amount of eligible benefits, the individual must provide documentation, which may include payments made or bills for medical items or services, lost employment income documentation, or a death certificate. In general, benefits under CICP are only paid after an individual has made a good faith attempt to obtain coverage from third-party payers, such as health insurance.

CICP compensation is only available when the Secretary of Health and Human Services issues a PREP Act declaration for a specific public health threat, thereby limiting legal liability for losses related to a covered countermeasure.[5] In March 2020, for example, the Secretary issued such a declaration for COVID-19 (see table 1).[6]

Table 1: Public Health Threats Triggering Eligibility for Compensation through the Countermeasures Injury Compensation Program (CICP), by Public Readiness and Emergency Preparedness Act (PREP Act) Declaration Date, as of December 2024

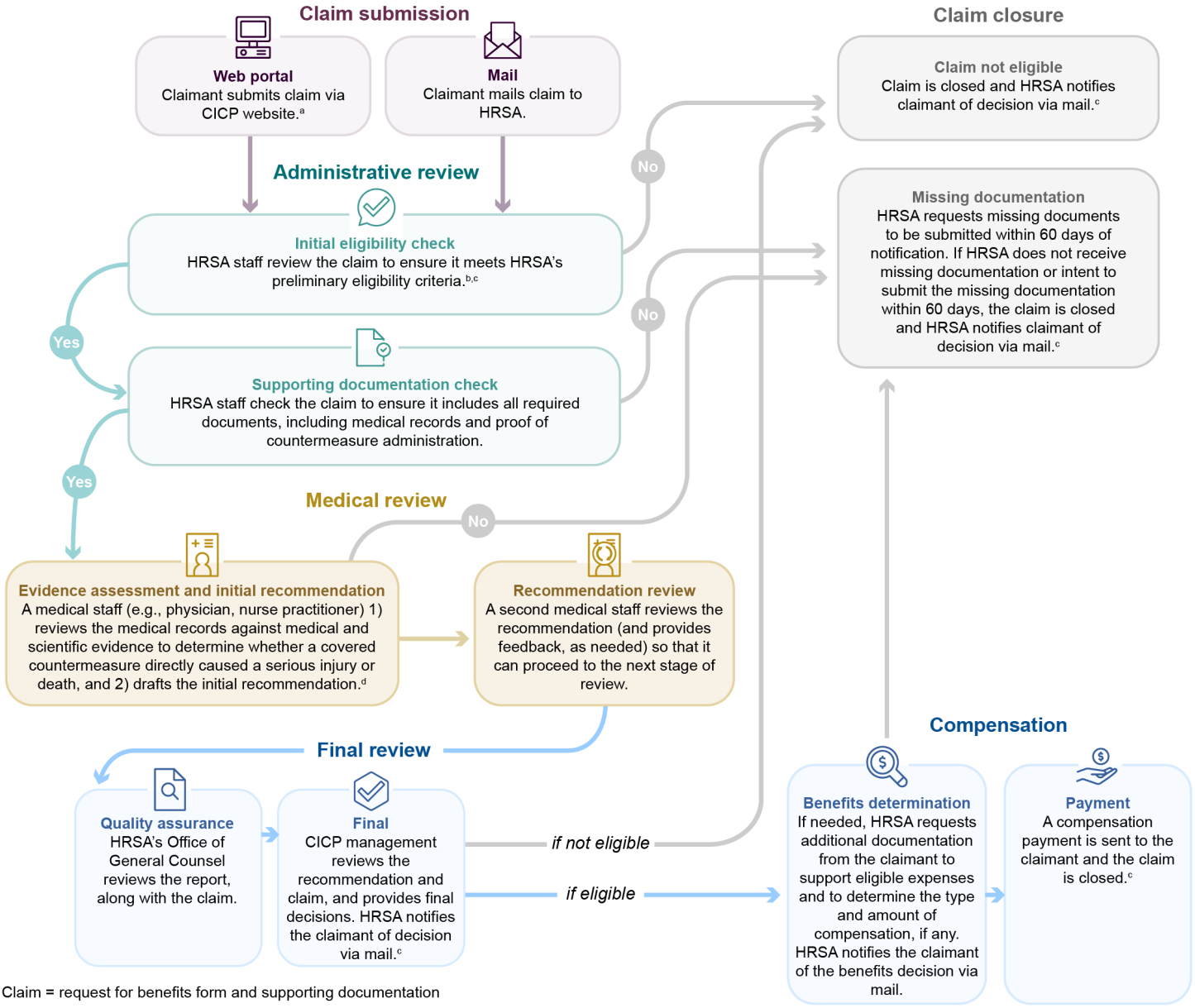
Eligible public health threats	Effective date of PREP Act declaration	Expiration date of PREP Act declaration
Anthrax	October 1, 2008	December 31, 2027
Acute radiation syndrome	October 10, 2008	December 31, 2027
Botulinum toxin	October 10, 2008	December 31, 2027
Pandemic influenza	October 10, 2008	December 31, 2027
Smallpox and other orthopoxviruses (e.g., mpox)	October 10, 2008	December 31, 2032
Ebola	December 3, 2014	December 31, 2028
Zika	August 1, 2016	December 31, 2027
Nerve agents and certain insecticides	April 11, 2017	December 31, 2027
COVID-19	February 4, 2020	December 31, 2029
Marburg	November 25, 2020	December 31, 2028

Source: GAO analysis of declarations made by the Secretary of Health and Human Services. I GAO-25-107368

What is HRSA's process for adjudicating a CICP claim?

Once a CICP claim is submitted, HRSA adjudicates each claim individually. HRSA's adjudication process includes an administrative review with an initial eligibility check and, if the claim is found eligible to proceed, a medical review to assess a claimant's medical records against medical and scientific evidence, such as published peer-reviewed literature and government reports. See figure 1 for more details on HRSA's process.

Figure 1: Health Resources and Services Administration's (HRSA) Process for Adjudicating Countermeasures Injury Compensation Program (CICP) Claims



Claim = request for benefits form and supporting documentation

Source: GAO analysis of HRSA documents and interviews with agency officials (data); RaulAlmu/stock.adobe.com (illustrations). | GAO-25-107368

[a]Prior to September 2021, claimants could only submit a request for benefits form, or letter of intent, and supporting documentation to HRSA by mail. For claimants who have set up an account through the CICP web portal, HRSA is able to provide an electronic status update.

[b]To be eligible for compensation, an individual must submit a request for benefits form, or letter of intent, within one year of the administration or use of a covered countermeasure, which is a countermeasure that is covered by a Public Readiness and Emergency Preparedness Act (PREP Act) declaration.

[c]The claimant can request reconsideration of HRSA's eligibility benefits decisions or the type and amount of benefits decision by submitting a request for reconsideration postmarked within 60 days of the original decision.

[d]Under the PREP Act, direct causation must be based on compelling, reliable, valid, medical and scientific evidence. 42 U.S.C. § 247d-6e(b)(4).

The PREP Act requires the Secretary of Health and Human Services to develop countermeasure injury tables that list and explain injuries that are presumed to be directly caused by a covered countermeasure on the basis of medical and scientific evidence and within set parameters.[7] For example, in the Pandemic Influenza Countermeasures Injury Table, Guillain-Barré syndrome, a condition that results in numbness and often paralysis, is listed as a serious physical injury caused by the H1N1 vaccine. The use of a countermeasure injury table may decrease the time and resources to review a claim as it is already determined that the injury can be directly caused by the administration or use of the

countermeasure, according to HRSA officials. HRSA has established countermeasure injury tables for pandemic influenza and smallpox, effective as of September 8, 2015, and September 15, 2021, respectively.[8] HRSA officials said they are in the process of developing countermeasure injury tables for other public health and security threats, such as COVID-19.

If a claimant believes that HRSA wrongly deemed their claim to be ineligible for compensation, or if they disagree with the amount of compensation, the claimant can request HRSA to reconsider its decision by submitting a request in writing.[9] According to HRSA regulations, no additional documentation may be submitted along with the request for reconsideration.

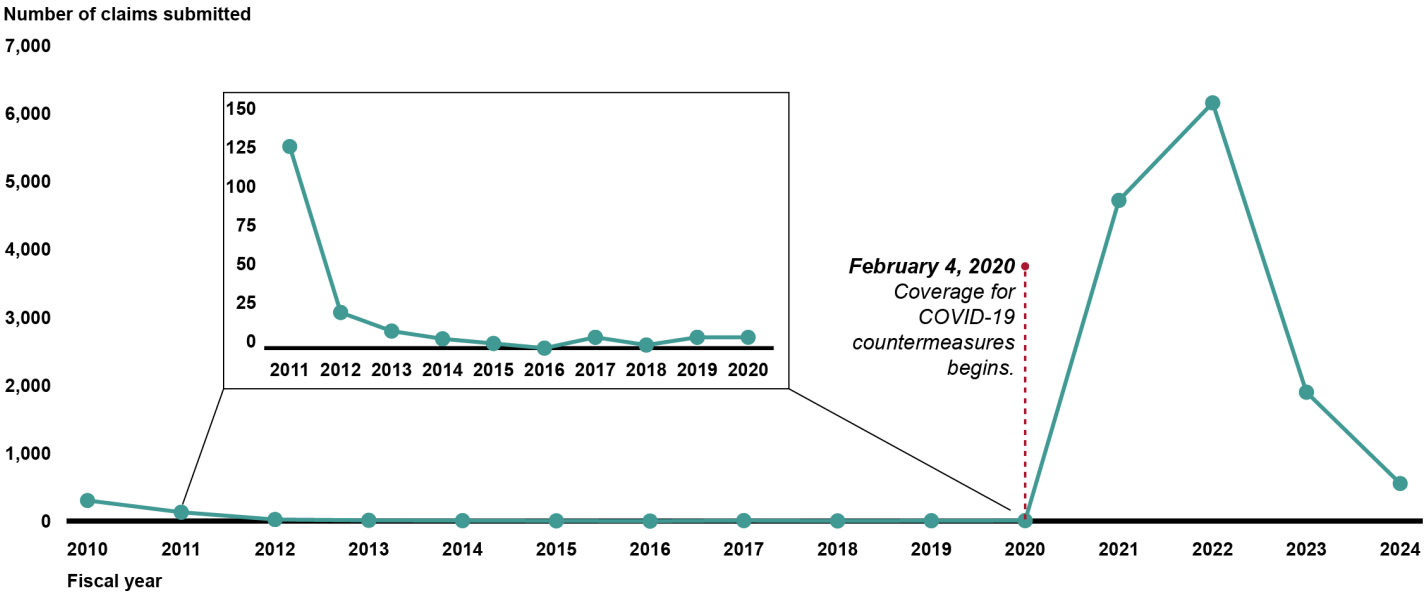
When HRSA receives a request for reconsideration, it convenes an independent, qualified panel to review HRSA's original determination. HRSA officials told us that the panels do not include CICP employees and are instead staffed with either contracted staff or U.S. Public Health Service Commissioned Corps officers, which may include physicians and nurses. The panel submits its findings and recommendations to the Associate Administrator of HRSA's Health Systems Bureau, who reviews the panel's recommendations and makes a final decision. This decision is sent to the claimant and is HRSA's final action on the request for reconsideration. Claimants may not seek additional administrative or judicial review of a decision made on a reconsideration.[10]

HRSA officials told us that a panel's review caseload often depends on the reason for the reconsideration. For example, for reconsiderations of an administrative review decision, such as missing a filing deadline or missing paperwork, a panel reviews 10 to 12 cases at a time. For reconsiderations of a medical review decision, however, officials told us that a panel typically reviews 2 to 3 cases at a time because of the significant amount of medical documentation to assess. According to HRSA officials, there have been 59 panels from March 2021 (when HRSA began receiving requests for reconsideration related to COVID-19) through June 2024.

How many and what types of claims has CICP received from 2009 through 2024?

Since CICP began accepting claims in October 2009, the program has received 13,824 claims, with the vast majority in response to the COVID-19 pandemic. Specifically, HRSA received about 27 times more claims in response to the COVID-19 pandemic than in the entire first decade of the program—13,333 compared to 491 claims, respectively. (See fig. 2.) Prior to the COVID-19 pandemic, HRSA received claims related to countermeasures administered or used for pandemic influenza (e.g., H1N1) and smallpox viruses, among other things.

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

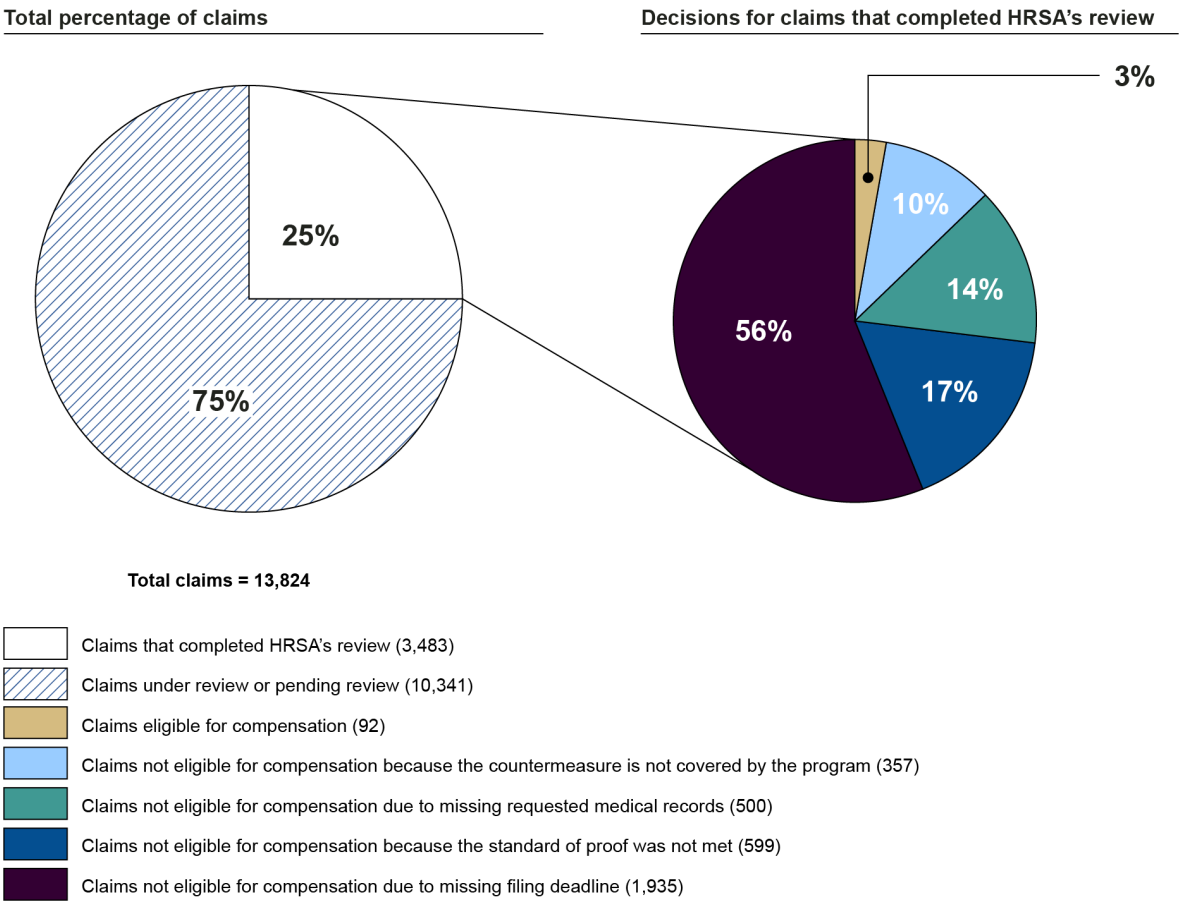


Source: GAO analysis of Health Resources and Services Administration data. | GAO-25-107368

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.

Decisions. HRSA made claims decisions for 3,483 of the 13,824 total CICP claims (25 percent) as of June 2024, the most recent data available at the time of our analysis. Of the 3,483 claims that have completed HRSA's adjudication process, 3 percent (92) were found eligible to receive compensation for a serious injury or death directly caused by a covered countermeasure. Fifty-two of the claims that received compensation were for serious injuries or deaths caused by COVID-19 countermeasures, 37 were for serious injuries caused by the H1N1 vaccine, and the remaining 3 were for serious injuries or deaths caused by smallpox and anthrax countermeasures. Missing the filing deadline was the most common reason for ineligible claim decisions. (See fig. 3.)

Figure 3: Countermeasures Injury Compensation Program (CICP) Claims Decisions, All Covered Countermeasures, as of June 2024



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

Note: Data reflect October 2009, when the agency began accepting CICP claims, through June 2024, the latest data available when we conducted our analysis.

Adjudication time frames. As of June 2024, HRSA data show that it took the agency 24 months on average (range of 5 to 39 months) to complete both the initial eligibility check and medical review needed to make a claim decision.[11] For those claims that were deemed ineligible after the initial eligibility check, HRSA took 14 months on average (range of 2 days to 38 months) to make that determination, as of June 2024.[12] HRSA officials noted that these review time frames include back-and-forth communication with claimants if additional documentation is necessary to make a determination, and claimants have 60 days to respond to each request. HRSA began tracking adjudication time frames in the summer of 2021.

Compensation awarded. As of June 2024, HRSA had paid 51 of the 92 claims eligible for compensation, totaling about $6,495,000. Most of the payments ($6,100,000) were for deaths or serious injuries, such as Guillain-Barré syndrome, caused by the H1N1 vaccine. These payments ranged from $31 to $2,295,930 per claim. About $419,000 in payments went to 14 claimants for serious injuries caused by COVID-19 countermeasures, such as myocarditis or myopericarditis, which are inflammatory heart conditions that can cause a decline in heart function. The payments related to COVID-19 countermeasures ranged from $1,032 to $370,376 per claim. As of June 2024, 41 claims eligible for compensation were pending a decision on the benefit amount.

How many requests has HRSA received to reconsider its claim decisions?

HRSA data showed that of the 3,484 claims that completed HRSA's adjudication process, 486 requests had been submitted to HRSA to reconsider CICP claim decisions, as of July 2024.[13] Nearly all of the requests were related to COVID-19 countermeasures and over 80 percent (394) were related to a claimant disagreeing with a decision made during the administrative review, such as missing a filing deadline or not providing supporting documentation.

Of these requests, HRSA's independent reconsideration panel reviewed 392 (81 percent) as of July 2024. Of these, the panel found that 389 (99 percent) remained ineligible for compensation and 3 claims (1 percent) had the decision reversed and were sent back to CICP to conduct a medical review. Forty-nine of these requests to reconsider claim decisions were waiting to be reviewed or pending a decision from HRSA.

What challenges has HRSA experienced operating CICP, including those related to COVID-19?

Nearly all of the challenges HRSA experienced operating CICP stem from the large influx of claims the agency received related to COVID-19 countermeasures and limited resources prior to fiscal year 2022, according to HRSA officials. These challenges were:

Shortage of staff to adjudicate large influx of claims. The agency did not have the number of staff needed to conduct administrative and medical reviews for the large volume of COVID-19 claims, according to HRSA officials. Officials told us that CICP had four staff at the start of the COVID-19 pandemic.

Outdated information systems to process large number of claims. HRSA officials told us that, at the beginning of the COVID-19 pandemic, individuals mailed claims to HRSA because there was no way for them to electronically submit them. Officials said when a mailed claim was received, staff manually entered the information into the claims management system. Additionally, a time-intensive step of the claims adjudication process—the medical review—is manually tracked outside of the agency's claims management system because it involves multiple steps to ensure a rigorous review, according to agency officials. Lastly, officials told us that all of HRSA's official communications with claimants, such as claim decisions and requests for additional information, are conducted via certified mail because HRSA does not have a secure direct two-way electronic mailbox to email claimants.

Limited medical and scientific evidence to base decisions about injuries or deaths allegedly caused by novel COVID-19 countermeasures. HRSA officials told us there was limited medical and scientific evidence concerning whether injuries or deaths were directly caused by covered COVID-19 countermeasures, in part, because the disease and related countermeasures were novel at the time. HRSA officials also told us the lack of medical and scientific evidence was challenging for medical reviewers to quickly determine whether there was causality between COVID-19 countermeasures and injuries and death. Instead, reviewers carefully considered the facts on a case-by-case basis to determine eligibility for benefits, adding time to the claim adjudication process.

What actions has HRSA taken to address challenges operating CICP, including those related to COVID-19?

HRSA took several actions to address challenges related to adjudicating the large influx of COVID-19 countermeasure injury claims. These actions generally responded to challenges related to staffing shortages, outdated information systems, and limited COVID-19 medical and scientific evidence.

Actions to address staffing challenges

Hired and contracted additional staff to expand capacity. HRSA hired 32 additional full-time staff in fiscal year 2022—an increase of 800 percent from the previous fiscal year—to help adjudicate the large influx of claims related to COVID-19 countermeasures. In addition to these 32 staff, HRSA officials told us they contracted with companies to expand the agency's ability to quickly scale medical review capacity as needed (see table 2).

Table 2. Countermeasures Injury Compensation Program (CICP) Staff Hiring and Attrition, Fiscal Years 2021-2024

	2021	2022	2023	2024[a]
Number of staff at start of year	4	4	35	36
Staff new hires	0	32	2	1
Staff attrition	0	1	1	8
Number of staff at end of year	4	35	36	29
Contracted medical reviewers	0	0	30	15

Source: GAO analysis of Health Resources and Services Administration information. I GAO-25-107368

[a]Fiscal year 2024 information is as of August 1, 2024.

These additional staff allowed CICP to initiate the adjudication of about 600 claims in fiscal year 2022 compared to 30 claim adjudications initiated in fiscal year 2021, according to HRSA's budget justification for fiscal year 2024. HRSA officials told us that with the current number of staff (29) as of fiscal year 2024, HRSA's target is to adjudicate 2,000 claims per year. According to HRSA data, the agency adjudicated 91 claims in fiscal year 2022, 1,177 claims in fiscal year 2023, and 1,924 claims in fiscal year 2024 (as of August 1, 2024). Assuming that HRSA can continue to retain enough staff to adjudicate 2,000 claims per year, the agency would finish reviewing all of the claims it has as of June 2024 in the next five years.

In September 2021, HRSA began contracting with a call center to expand its ability to provide claimants with general program information and update a claimant's email or mailing address. At the beginning of the COVID-19 pandemic, CICP had one staff member available for these purposes. According to HRSA documents, HRSA has the option to use these call center services through September 2026.

Developed new staff guidance and support program. HRSA developed guidance and flowcharts for administrative and medical review processes to quickly onboard new staff. For example, HRSA created instructions to determine if a claim was filed within the appropriate time period and checklists for medical reviewers to write recommendations consistently and efficiently. HRSA also developed a peer-to-peer support system pairing new staff during training to discuss guidance and elevate questions to leadership when appropriate. HRSA officials told us they took these actions to quickly train a large number of new staff in a program with few experienced staff.

Actions to address information system challenges

Launched web portal for claim submissions and status updates. In September 2021, HRSA launched a web portal where individuals can submit and check the status of their claim, according to officials. Officials told us that

information submitted through the web portal is automatically uploaded into HRSA's claims management system. Individuals can still submit claims via mail. From October 2009 through May 2024, HRSA officials said they received about 41 percent of claims through the CICP web portal and about 59 percent via mail.

Implemented software to upload mailed submissions. In September 2023, HRSA implemented a software system that automatically uploads information from mailed claims into HRSA's claims management system. According to HRSA officials, staff scan the submission and the software uploads the information in seconds compared to the 20-to-30 minutes it previously took for staff to manually enter information into the claims management system.

Actions to address COVID-19 medical and scientific evidence challenges

Started developing COVID-19 Countermeasure Injury Table. HRSA officials said the agency began initial development of a countermeasure injury table to facilitate quicker reviews of medical evidence for COVID-19 countermeasure injury and death claims in February 2022. In developing the table, HRSA requested the National Academies of Sciences, Engineering, and Medicine review and report on the evidence regarding specific potential harms related to COVID-19 vaccines in September 2022. This report was issued in April 2024.[14] HRSA planned to publish the proposed injury table in November 2024, according to the Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions, the most recent agenda available as of December 2024.[15]

Developed medical report template. To promote consistency in writing medical recommendations across COVID-19 countermeasure injury claims, HRSA developed a medical report template in September 2023. The template enables medical reviewers to more easily assess alleged injuries or death against available peer-reviewed medical and scientific literature. HRSA officials told us this template was incorporated as part of training to onboard new staff and helps medical reviewers efficiently and consistently apply the standard of evidence required by the PREP Act to each claim.

What steps has HRSA taken to prepare CICP for future public health emergencies?

HRSA has taken steps to better prepare CICP to adjudicate medical countermeasure injury compensation claims for future public health emergencies and risks of such emergencies. Specifically, HRSA has taken steps to 1) improve its claims management system; 2) ensure staffing can be scaled up quickly; and 3) increase coordination with other public health emergency response agencies.

Improving claims management system. According to HRSA documents and officials, the agency plans to launch a new claims management system in 2025 that will track and upload information from the medical review into the system, which is not possible with the agency's current system.

HRSA officials told us that the new claims management system will include a secure electronic inbox that allows for direct two-way communication with claimants. According to officials, the only secure way HRSA can currently communicate claim decisions and requests for additional information with claimants is through mail that requires a signature upon receipt. HRSA officials told us this two-way communication will speed up the review process and allow claimants to receive personal responses to case-specific questions in real time.

Ensuring staffing is quickly scalable. In July 2022, HRSA established a blanket purchase agreement for contracted medical expert services that can be used on an as-needed basis, such as when the program needs additional

medical reviewers to support processing an influx of CICP claims. HRSA officials said that the agency can only execute this blanket purchase agreement if there is funding available to pay for these services. According to HRSA officials, CICP is funded through appropriations, of which the first direct appropriation was received in fiscal year 2022. This means HRSA must wait for additional appropriations or transfer funds to increase spending. If funding is available, however, this agreement would provide HRSA flexibility to respond to future public health emergencies (or risks of such emergencies), for example, by quickly increasing staffing to meet program needs.[16]

HRSA officials told us different potential CICP funding models may better position CICP to quickly scale up staffing during future public health emergencies. For example, officials told us a funding model similar to the agency's Vaccine Injury Compensation Program (VICP) would allow HRSA to scale its CICP operations in proportion to need during a future public health emergency. VICP pays for compensation of injuries or deaths from certain routine vaccines and operations through a trust fund that is financed by an excise tax on vaccines covered by the program.[17] (See app. I for information about VICP and how it compares to CICP).

Increasing interagency coordination. HRSA is increasing its participation in interagency workgroups to help ensure that CICP is included in discussions about timely and coordinated responses to public health emergencies (or risks of such emergencies), according to HRSA officials. For example, officials told us they are involved in working groups with the Administration for Strategic Preparedness and Response, within HHS, addressing emerging H5N1 and mpox outbreaks. Through participation in these workgroups, officials told us they are learning what types of covered countermeasures may be deployed if these outbreaks become public health emergencies so they can prepare for potential injury or death claims.

Additionally, HRSA officials told us they are working with an interagency vaccine working group headed by the Office of the Assistant Secretary for Health to include information on HRSA's vaccine-related compensation programs, CICP and VICP, in the next iteration of the Vaccines National Strategic Plan. This interagency vaccine working group includes agencies such as the Centers for Disease Control and Prevention, the Food and Drug Administration, and the National Institutes of Health.

What programs exist in foreign countries to compensate individuals for injuries or deaths related to COVID-19 vaccines?

As of October 2024, 38 foreign countries and three international programs operate medical injury compensation programs for injuries or deaths from COVID-19 vaccines, according to research from the University of Oxford.[18] Nine of the 38 programs in foreign countries were formed during the COVID-19 pandemic. Additionally, some of these 38 programs provide compensation for injuries or deaths from routinely administered vaccines or pharmaceuticals, such as Canada's Vaccine Injury Support Program and the Swedish Pharmaceutical Insurer, according to program documents and officials.

The five selected medical injury compensation programs we reviewed—four from foreign countries and one international program representing 92 foreign countries—have an administrative process for adjudicating claims. Under this process, claimants submit a form and supporting documentation to prove eligibility and compensation amounts and can appeal a claim decision about compensation. The five programs have varying standards for the causal link required between the vaccine and claimed injury. These five programs also differ by date of implementation, filing deadline, and available benefits (see table 3).

Table 3. Description of Select Foreign Countries' and International Medical Injury Compensation Programs

Name of Program (Country or International)	Year of implementation	Program administrator	Products covered	Filing deadline	Benefits available
Vaccine Injury Support Program (Canada)	2021	Contracted claims administrator	COVID-19 and routinely administered vaccines	3 years from vaccine administration or adverse event occurrence	Health care provider fees and uncovered medical expenses, financial losses, death benefits, funeral costs
Vaccine Injury Financial Assistance Programme for COVID-19 Vaccination (Singapore)	2021	Federal government	COVID-19 vaccines	3 years from adverse event occurrence	Fixed sum for severe disability, death, inpatient hospital care[a]
Swedish Pharmaceutical Insurer (Sweden)	1978	Independent pharmaceutical insurer[b]	COVID-19 and routinely administered vaccines, and pharmaceutical products	10 years from vaccine administration or use of drug	Loss of income, pain and suffering compensation, permanent injury compensation
Compensation and Satisfaction for Loss or Damage as a Consequence of Vaccination (Switzerland)	2016[c]	Federal government	COVID-19 and officially ordered or officially recommended vaccines	5 years from vaccine administration or by age 21	Compensation and satisfaction for loss and damage (e.g., loss of income and cost for treatment)
COVAX No-Fault Compensation Program for Advance Market Commitment Eligible Economies[d] (International)	2021	Contracted claims administrator	COVID-19 vaccines	Up to 5 years from vaccine administration[e]	Fixed sum for permanent injury, death, hospital care[f]

Source: GAO analysis of the University of Oxford's COVID-19 Vaccine No-Fault Compensation Schemes Program and selected foreign countries' and international medical injury compensation program information and interviews with officials. | GAO-25-107368

[a]Payments depend on the severity of the adverse reaction.

[b]Sweden's independent claims administrator (Swedish Pharmaceutical Insurer) was created for companies and organizations that work with pharmaceuticals in Sweden. Owning a share in this company ensures patients using any shareholder's pharmaceutical product the right to have their injury investigated by the Swedish Pharmaceutical Insurer and if relevant, receive compensation. Almost all companies and organizations that provide pharmaceutical products in Sweden (99.7 percent) are shareholders.

[c]Switzerland had a pre-existing injury compensation program for mandatory or officially recommended vaccines starting in 1970, which was administered at the canton (i.e., state) level. In 2016, the program was transferred to the federal level and the federal government became the administrator.

[d]The COVAX No-Fault Compensation Program for Advanced Market Commitment Eligible Economies (COVAX) receives claims related to serious injuries or deaths from COVID-19 vaccines earmarked for delivery through the COVAX facility to 92 middle- and low-income countries up to and inclusive of June 30, 2023.

[e]Claimants must have received the vaccine within 2 years from the date on which the vaccine was first put into circulation by the manufacturer in any country (whether within or outside the framework of the COVAX facility) following regulatory approval or an emergency use authorization of such vaccine by any regulator. Depending on the date of administration of a vaccine, claimants have 5 years from the date of administration to file a claim. All claims must be submitted before June 30, 2027, when the program's application process will come to an end.

[f]Calculations to determine payment include factors such as the severity of injury and cost of living and a fixed per-day payment for hospital stays up to 60 days.

Officials from the selected foreign countries told us about some unique characteristics of their medical injury compensation programs. For example:

- A Swedish official told us that claimants can provide the program with power of attorney to obtain medical records needed to adjudicate their claim, which speeds up the process.
- Canadian officials told us that while the Public Health Agency of Canada funds and sets the policies for Canada's medical injury compensation program, this program is administered by a third-party for-profit organization.
- Singaporean officials told us compensation through their program is based on severity of the injury with three different payment tiers. The highest amount of

compensation, according to officials, is reserved for permanent severe disability and death.

- Swiss officials told us claims are not adjudicated in the context of a dedicated program, but by cross-disciplinary staff from the federal Department of Home Affairs.

To what extent have selected foreign countries taken actions to prepare their medical injury compensation programs for future public health emergencies?

Officials from three of the four selected foreign countries said they have taken or plan to take actions in response to their experiences operating these programs during the COVID-19 pandemic. For example, according to officials, two programs experienced a large influx of claims in response to the COVID-19 pandemic and one program balanced adjudicating claims while simultaneously setting up their medical injury compensation program. According to officials, actions in response to experiences during the pandemic will help prepare their medical compensation programs for future public health emergencies, and include the following:

Creating contracts to quickly hire staff. An official from Sweden, for example, told us it was important to have contracts in place to hire additional medical reviewers as needed. According to this official, because their program had these contracts in place prior to the COVID-19 pandemic, they were able to quickly hire additional staff without disrupting the average time for adjudicating claims despite experiencing an influx of claims for COVID-19 vaccines.

Evaluating programs. Officials from Singapore and Canada told us they plan to evaluate their newly created programs, which were created during the COVID-19 pandemic, to prepare for future public health emergencies. Officials from Canada told us that setting up their program was particularly difficult due to the large influx of claims they experienced during the pandemic. Additionally, officials from Canada told us that they plan to meet with other countries to learn more about their medical injury compensation programs and what these countries have learned in response to their experiences operating these programs during the COVID-19 pandemic. Officials from Singapore told us their evaluation will include communications on complex topics like adverse events and causation.

Agency Comments

We provided a draft of this report to HHS for review and comments. We also provided excerpts of this report to the five foreign selected medical injury compensation programs we examined for their review and comment. HHS and the five foreign programs provided technical comments, which we incorporated as appropriate.

How GAO Did This Study

We reviewed relevant HRSA documentation, including regulations, policies, guidance, training materials, and budget documents. We also interviewed agency officials about CICP.

We analyzed HRSA data on CICP claims submitted from October 2009 (the date CICP began accepting claims) through June 2024 (the most recent data available at the time of our analysis). Additionally, we analyzed HRSA data on requests to reconsider CICP claim decisions from January 2022 (the date CICP established a comprehensive data set for reconsideration requests) through July 2024 (the most recent data available at the time of our analysis). To assess the reliability of these data, we reviewed relevant documentation, interviewed HRSA officials, and performed electronic testing for missing values and obvious errors. We found these data to be sufficiently reliable for our reporting purposes.

In addition, we reviewed documentation from University of Oxford's COVID-19 Vaccine No-Fault Compensation Schemes Project that identifies and describes all known medical injury compensation programs that include COVID-19 vaccines worldwide. We identified this as the only available source that mapped and categorized all known worldwide medical injury compensation programs.

We conducted interviews with officials and reviewed documents from a non-generalizable sample of four foreign countries—Canada, Singapore, Sweden, and Switzerland—that have medical injury compensation programs that include COVID-19 vaccines. We selected these countries for variation in length of time of program operation and claim filing deadlines, and variation in COVID-19 vaccine administration rates. These selection factors provided context for a variety of program experiences and actions. For example, programs in countries with higher COVID-19 vaccination rates may have higher claims volumes, and therefore, different experiences than programs in countries with lower vaccination rates.

We also interviewed officials from one international program—the COVAX No-Fault Compensation Program for Advanced Market Commitment Eligible Economies. We selected this program because of the three international programs, it covered the largest number of low- and middle-income countries. Information from these interviews cannot be generalized to COVID-19 medical injury compensation programs in other countries.

We conducted this performance audit from February 2024 to December 2024 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

List of Addressees

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Chair
The Honorable Susan Collins
Vice Chair
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
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Committee on Oversight and Accountability
House of Representatives

The Honorable Jason Smith
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The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
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We are sending copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

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Appendix I: Comparison of Countermeasures Injury Compensation Program and National Vaccine Injury Compensation Program

The Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services, administers two injury compensation programs. The Countermeasures Injury Compensation Program (CICP) compensates individuals for serious physical injuries or deaths directly caused by the administration or use of covered countermeasures, including certain vaccines and other medical products. The National Vaccine Injury Compensation Program (VICP) compensates individuals for injuries or deaths related to certain vaccines recommended for routine administration to children or pregnant women, such as measles, mumps, and rubella vaccines. While HRSA administers both programs, they differ in authorization, operation, and funding (see table 4).

Table 4: Health Resources and Services Administration's (HRSA) Countermeasures Injury Compensation Program (CICP) and National Vaccine Injury Compensation Program (VICP)

Program elements	CICP	VICP
Program authorization	Public Readiness and Emergency Preparedness Act (PREP Act)	National Childhood Vaccine Injury Act of 1986
Program funding	Appropriations	Excise taxes on covered vaccines, which are appropriated from the Vaccine Injury Compensation Trust Fund to HRSA, the Department of Justice, and the U.S. Court of Federal Claims
Products covered	Covered countermeasures, which are defined in statute and described in PREP Act declarations for public health threats (e.g., COVID-19)[a]	Vaccines included in HRSA's Vaccine Injury Table (e.g., measles vaccine)[b]
Claim submission	Submit request form and documentation to HRSA	File petition and documentation with the U.S. Court of Federal Claims and HRSA
Claim adjudication	Administrative process	Judicial process
Claim decisions	HRSA makes decision (under delegated authority from the Secretary of Health and Human Services)	Special Masters (or judges) of U.S. Court of Federal Claims make decision
Claim appeals	Administrative reconsideration upon request. No judicial appeal permitted	Appeal by either party to the U.S. Court of Appeals for the Federal Circuit

Source: GAO review of HRSA information and relevant statutes and regulations. I GAO-25-107368

[a]See 42 U.S.C. § 247d-6e(e)(1) (referring to 42 U.S.C. § 247d-6d(i)(1)) and 42 C.F.R. § 110.3(f) (2023). The Secretary of Health and Human Services may issue a PREP Act declaration for a specific public health threat limiting legal liability for losses related to a covered countermeasure. 42 U.S.C. § 247d-6d.

[b]The Vaccine Injury Table is set forth in statute under 42 U.S.C. § 300aa-14. The Secretary of Health and Human Services is authorized to issue regulations to modify the Vaccine Injury Table and is required to revise the table when the Centers for Disease Control and Prevention recommends a vaccine for routine

administration to children or pregnant women. A federal tax must be imposed on a category of vaccine for a vaccine to receive VICP coverage.

Endnotes

[1]Specifically, the CARES Act requires us to monitor and oversee the federal government's efforts to prepare for, respond to, and recover from the pandemic. Pub. L. No. 116-136, § 19010(b), 134 Stat. 281, 580 (2020). The American Rescue Plan Act of 2021 also includes a provision for us to conduct oversight of the COVID-19 response. Pub. L. No. 117-2, § 4002, 135 Stat. 4, 78. See https://www.gao.gov/coronavirus for our reports related to the COVID-19 pandemic.

[2]42 C.F.R. § 110.10 (2023). Covered countermeasures can include vaccines, medications, devices or other items used to prevent diagnose, mitigate, treat, cure, or limit the harm of a pandemic or epidemic, or a chemical, biological, radiological, nuclear agent threat. Countermeasures covered under CICP are defined in statute and regulation and are described in PREP Act declarations. See 42 U.S.C. § 247d-6e(e)(1) (referring to 42 U.S.C. § 247d-6d(i)(1)) and 42 C.F.R. § 110.3(f) (2023).

[3]Injured countermeasure recipients may be eligible for medical benefits or benefits for lost employment income, or both. Survivors of countermeasure recipients who died as a direct result of covered injuries may be eligible for death benefits. Executors or administrators on behalf of the estate of deceased injured countermeasure recipients may be eligible for medical benefits or benefits for lost employment income, or both. See 42 C.F.R. § 110.30 (2023). HRSA regulations use the term "requester" to refer to an injured countermeasure recipient, survivor, or the estate of a deceased injured countermeasure recipient. In this report, we refer to these parties as individuals or claimants.

[4]Under the PREP Act, direct causation must be based on compelling, reliable, valid, medical and scientific evidence. 42 U.S.C. § 247d-6e(b)(4). See also 42 C.F.R. § 110.20(c) (2023). In this report, we use the term "medical and scientific evidence" to refer to compelling, reliable, valid, medical and scientific evidence.

[5]The PREP Act was enacted as part of the Department of Defense, Emergency Supplemental Appropriations to Address Hurricanes in the Gulf of Mexico, and Pandemic Influenza Act, 2006, Pub. L. No. 109-148, div. C, 119 Stat. 2680, 2818–32 (2005) (codified as amended at 42 U.S.C. §§ 247d-6d and 247d-6e).The Secretary of Health and Human Services may make a PREP Act declaration if the Secretary determines that a disease or other health 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 constitute an emergency in the future. 42 U.S.C. § 247d-6d(b)(1). This determination is separate from a public health emergency declaration under section 319 of the Public Health Service Act.

[6]85 Fed. Reg. 15,198 (Mar. 17, 2020). The declaration was effective as of February 4, 2020.

[7]See 42 U.S.C. § 247d-6e(b)(5). Countermeasure injury tables list injuries that are presumed to be caused by a covered countermeasure. If the first sign or symptom of an injury occurs within the listed time period and at the level of severity required, there is a presumption that the covered countermeasure caused the injury, unless another more likely cause is demonstrated.

[8]See 42 C.F.R. § 110.100 (2023) for the Pandemic Influenza Countermeasures Injury Table and Smallpox Countermeasures Injury Table.

[9]To request reconsideration of HRSA's claim decision, the claimant must submit a request for reconsideration in writing that is postmarked within 60 calendar days of the original decision. The request must describe the reasons why the decision should be reconsidered. 42 C.F.R. § 110.90 (2023).

[10]See 42 U.S.C. § 247d-6e(b)(4) and 42 C.F.R. § 110.92(a) (2023).

[11]The median review time was 25 months. HRSA does not have time frames for the medical review for claims adjudicated prior to June 2021.

[12]The median review time was 13 months. HRSA does not have time frames for the initial eligibility check for claims adjudicated prior to August 2021.

[13]HRSA does not have a comprehensive data set on requests for reconsideration prior to January 2022.

[14]National Academies of Sciences, Engineering, and Medicine, *2024 Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration* (Washington, D.C.: The National Academies Press, 2024).

[15]HRSA officials told us that CICP countermeasure injury tables must be published through the federal rulemaking process. This process includes periods of review, public comment, and response, which can make timelines difficult to predict.

[16]CICP is funded by the Covered Countermeasure Process Fund, which covers HRSA's costs for operating CICP and for paying eligible claims for compensation.

[17]The Department of the Treasury collects the excise taxes for VICP and manages the trust fund.

[18]The University of Oxford's COVID-19 Vaccine No-Fault Compensation Scheme Project mapped out all known medical injury compensation programs worldwide that cover COVID-19 vaccines and identified 38 countries with vaccine injury compensation programs, including Hong Kong and Taiwan.