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Health Systems Bureau  
Rockville, MD 20857

**DATE:** January 5, 2024  
**TO:** Dan Cline, OMB Desk Officer  
**FROM:** Joella Roland, HRSA Information Collection Clearance Officer

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**Request:** The Health Resources and Services Administration (HRSA) Health Systems Bureau requests approval for changes to the Countermeasures Injury Compensation Program Information Collection (OMB 0915-0334 expiration date 04/30/2026).

**Purpose:** The Countermeasures Injury Compensation Program (CICP) provides compensation for covered serious injuries or deaths that occur as the result of the administration or use of certain countermeasures. CICP regulations require that individuals (requesters) submit the medical records necessary to determine whether a covered injury was sustained as a direct result of a countermeasure and to make a determination of benefits. Often, the CICP receives incomplete Request for Benefits (RFB) packages per the CICP's currently approved Information Collection Request (ICR). Without a complete Request for Benefits Package (Request Package), the CICP cannot decide whether an individual is eligible for program benefits. In addition, the CICP now has the capability to accept RFB documentation online to expedite RFB processing, and eligibility and benefits determinations.

This request will communicate to CICP requesters that required documentation or information is missing from their Request Package. The CICP intends to notify CICP requesters in writing to ensure that they submit the required RFB documentation. This request also includes updated language to ICR documents informing requesters that documentation to complete their Request Package can now be submitted online.

This memo explains the changes and the rationale.

**Changes:** **Background**

The CICP Administrative Implementation regulations (42 CFR Part 110) establish the procedures by which individuals may submit RFBs under the CICP. This collection of information provides data and documentation that will be used by the Secretary to determine that the RFB meets the requirements of the CICP. Each Request Package must include the required documentation for the relevant individual described in §§ 110.10-110.11 in order for the Secretary to make a determination as to the requester's eligibility to receive benefits. The following regulations apply to the communications changes requested.

**42 CFR 110.40-110.41 and 110.44-110.45 Filing a Request Package**

The Request Package comprises the: Request Form, Authorization for Use or Disclosure of Health Information Form, medical records, Lost Employment Income Certification, Unreimbursed Medical Expenses Certification, and accompanying documentation to determine eligibility for benefits.

**42 CFR 110.50-110.53 Documentation Needed for the Secretary to Determine Eligibility.**

Requesters (or their representatives) must submit appropriate documentation to allow the Secretary to determine if requesters are eligible for Program benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or the executors/administrators of the estates of deceased injured countermeasure recipients.

All requesters (or their representatives) must submit, or authorize their health care providers to submit, medical records sufficient to demonstrate that a covered injury was sustained by a covered countermeasure.

**42 CFR 110.60-110.63 Documentation Needed for the Secretary to Calculate Benefits.**

Requesters who are deemed eligible for benefits by the Secretary must submit documentation as specified in section 42 CFR 110.60-110.63 to allow the Secretary to determine the type(s) and amounts of benefits, if any, that will be paid to the requester. This documentation is in addition to the documentation submitted under §§ 110.50-110.53. This includes documentation needed to calculate benefits for reasonable and necessary medical services or items, benefits for lost employment income, and death benefits. This documentation will vary somewhat depending on whether the requester is an injured countermeasure recipient, a survivor, or an

estate of a deceased injured countermeasure recipient (through its executor/administrator). Since the Program's payment of benefits is secondary to all other third-party payers, the documentation requirements include information about any third-party payers that may have an obligation to pay for such benefits.

### **Proposed Changes**

Table A lists instruments that are needed to facilitate the processing of CICP claims. The instruments are follow-up letters to inform requesters that their submitted Request Package is incomplete or missing required documentation for the CICP to make medical and benefits eligibility determinations and calculate benefits for eligible requesters. All instruments on the previous Health Systems Bureau letterhead have been placed on the updated Health Systems Bureau letterhead.

Instrument 1 is used by the CICP to identify gaps in the submitted Request Package and instructs the requester to submit the required documentation.

Instrument 2 is a follow-up letter requesting documentation that is required to ensure the Request Package is complete before the package is sent to a CICP medical reviewer.

Instrument 3 is a follow-up letter requesting documentation that is required to ensure the Request Package includes all medical documentation. This letter is sent when a CICP medical reviewer has performed a detailed review of the submitted medical records and there are still gaps in the required medical documentation.

Instrument 4 is a follow-up letter requesting required medical documentation as supported by CICP regulations.

Instrument 5 is a form template that facilitates a response to requests for CICP-required documentation in Instruments 1-4.

Instrument 6 is a follow-up letter requesting documentation that is required to ensure the Request Package includes all documents necessary to calculate CICP benefits. This letter will be sent when a CICP benefits specialist performs a detailed review of the submitted benefits documentation and there are still gaps in the required documentation.

Instrument 7 is a follow-up letter that provides 60-days for a requester to submit any additional documentation they would like to be considered in the medical review. This letter is sent when a CICIP medical reviewer has performed a detailed review of the submitted medical records and provides them with their last opportunity to submit additional records.

Instruments 8 through 20 are existing and approved instruments. The CICIP mail stop changed due to a move within the same building and this mail stop change is included. Additionally, the CICIP is adding clarifying language to these documents to assist requesters in submitting their Request Package, and informing requesters that the instrument can be submitted online at [injurycompensation.hrsa.gov](https://injurycompensation.hrsa.gov).

Instruments 21 through 24 are existing and approved instruments. The CICIP mail stop changed due to a move within the same building and this mail stop change is included.

**Time Sensitivity:** The data collection changes must be completed in a timely manner to ensure that communication can continue with requesters. Approval of these changes is needed by January 31, 2024, to implement changes in communication with requesters.

**Burden:** The changes included herein do not change the estimated reporting burden for requesters. Making these changes will allow HRSA to improve the processing of requests for CICIP benefits.

**PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES:**

**Table A**

<b>Instrument</b>	<b>Change implemented</b>	<b>Rationale</b>
1. Admin 60-day Letter Template	A new follow-up letter requesting required documentation as supported by CICIP regulations.	The letter requests documentation that is required to ensure the request package is complete before the package goes to a medical reviewer.
2. Insufficient Documentation – Blank RFB Form	A new follow-up letter requesting a required completed RFB form as supported by CICIP regulations.	The letter requests documentation that is required to ensure the request package is complete before the package is sent to a CICIP medical reviewer.
3. Insufficient	A new follow-up letter	The letter requests documentation

Documentation – Final 60-day Letter	requesting required medical documentation as supported by CICIP regulations.	that is required to ensure the request package includes all medical documentation. This letter is sent when a CICIP medical reviewer has performed a detailed review of the submitted medical records and there are still gaps in the required medical documentation.
4. Insufficient Documentation – Initial 60-day Letter	A new follow-up letter requesting required medical documentation as supported by CICIP regulations.	The letter requests documentation that is required to ensure the request package includes all medical documentation. This letter is sent when a CICIP medical reviewer has performed an initial review of the submitted medical records and there are readily apparent gaps in the medical records that preclude a detailed review of the claim.
5. Response Form	A new template is attached to the above letters that provides instructions on how to respond to the request contained in the letter.	This template facilitates a response to requests for CICIP required documentation in the above letter templates.
6. Insufficient Records – Benefits Determination Letter	A new follow-up letter requesting required benefits determination documentation as supported by CICIP regulations.	The letter requests documentation that is required to ensure the request package includes all benefits determination documentation. This letter is sent when a CICIP benefits specialist has performed an initial review of the submitted benefits determination documentation and there are readily apparent gaps in the documentation that preclude a detailed review of the claim.

7. Medical Last Chance Letter	A new follow-up letter providing the last 60-day opportunity for additional medical or other documentation to be submitted.	The letter provides a 60-day window to submit any additional documentation that requesters would like to be considered in the medical review. This letter is sent when a CICP medical reviewer has performed a detailed review of the submitted medical records and provides them with their last opportunity to submit additional medical records or other documentation.
8. Recipient Requester Package: Compensation Letter	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p> <p>The letterhead template has been updated.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p> <p>HRSA has recently changed letterhead, so this form has been updated to reflect this change.</p>
9. Recipient Requester Package: Attachment 1. Documentation Required to Reimburse or Pay for Medical Expenses and/or Lost Employment Income	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
10. Recipient Requester Package: Attachment 2: Unreimbursed Medical Expenses Certification	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
11. Recipient Requester Package: Attachment 3. Lost Employment Income	Language was added to provide requesters with a method of online submission of required documentation.	The online submission option provides an alternate option to submit required documentation.

Certification	The address was updated to reflect the new mail stop address.	The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.
12. Estate Package: Compensation Letter	Language was added to provide requesters with a method of online submission of required documentation.  The address was updated to reflect the new mail stop address.  The letterhead template has been updated.	The online submission option provides an alternate option to submit required documentation.  The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.  HRSA has recently changed letterhead, so this form has been updated to reflect this change.
13. Estate Package: Attachment 1. Compensation Attachment	Language was added to provide requesters with a method of online submission of required documentation.  The address was updated to reflect the new mail stop address.	The online submission option provides an alternate option to submit required documentation.  The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.
14. Estate Package: Attachment 2. Unreimbursed Medical Expenses Certification	Language was added to provide requesters with a method of online submission of required documentation.  The address was updated to reflect the new mail stop address.  The letterhead template has been updated.	The online submission option provides an alternate option to submit required documentation.  The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.  HRSA has recently changed letterhead, so this form has been updated to reflect this change.
15. Estate Package: Attachment 3. Lost Employment Income Certification	Language was added to provide requesters with a method of online submission of required documentation.  The address was updated to reflect the new mail stop address.	The online submission option provides an alternate option to submit required documentation.  The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.
16. Survivor Package: Compensation Letter	Language was added to provide requesters with a	The online submission option provides an alternate option to

	<p>method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop in address.</p>	<p>submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
<p>17. Survivor Package: Attachment 1. Certification of Status for Death Benefit - Standard Calculation</p>	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
<p>18. Survivor Package: Attachment 2. Certification of Status for Death Benefit – Alternative Calculation</p>	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
<p>19. Survivor Package: Attachment 3. Death Benefit Certification of Relationship</p>	<p>Language was added to provide requesters with a method of online submission of required documentation.</p> <p>The address was updated to reflect the new mail stop address.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move.</p>
<p>20. Certification Regarding Medical Records</p>	<p>Language was added to provide requesters with a method of online submission of required documentation and to include the mailing address directly on the form.</p> <p>The mailing address was previously included in a supplemental document but has been added for reference to this document.</p>	<p>The online submission option provides an alternate option to submit required documentation.</p> <p>The CICP has added the online portal link and the entire mailing address to this form to more clearly communicate where to return the document.</p>
<p>21. Request for Benefits Form - Spanish</p>	<p>Information about submitting online, and the current address was updated</p>	<p>The CICP has changed its mail stop due to a move within the same building and is adjusting the mail</p>

	to reflect the new mail stop.	stop to reflect this move. Language including the online link for electronic submission has also been added.
22. Request for Benefits Instructions – Spanish	Information about submitting online, and the current address was updated to reflect the new mail stop.	The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move. Language including the online link for electronic submission has also been added.
23. Authorization for Use or Disclosure of Health Information Form – Spanish	Information about submitting online, and the current address was updated to reflect the new mail stop.	The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move. Language including the online link for electronic submission has also been added.
24. Authorization for Use or Disclosure of Health Information Instructions – Spanish	Information about submitting online, and the current address was updated to reflect the new mail stop.	The CICP has changed its mail stop due to a move within the same building and is adjusting the mail stop to reflect this move. Language including the online link for electronic submission has also been added.

**Attachments:**

1. Admin 60-day Letter Template
2. Insufficient Documentation – Blank RFB Form
3. Insufficient Documentation – Final 60-day Letter
4. Insufficient Documentation – Initial 60-day Letter
5. Response Form
6. Insufficient Records – Benefits Determination Letter
7. Medical Last Chance Letter
8. Recipient Requester Package: Compensation Letter
9. Recipient Requester Package: Attachment 1: Documentation Required to Reimburse of Pay for Medical Expenses and/or Lost Employment Income
10. Recipient Requester Package: Attachment 2: Unreimbursed Medical Expenses Certification
11. Recipient Requester Package: Attachment 3: Lost Employment Income Certification
12. Estate Package: Compensation Letter
13. Estate Package: Attachment 1: Compensation Attachment
14. Estate Package: Attachment 2: Unreimbursed Medical Expenses Certification
15. Estate Package: Attachment 3: Lost Employment Income Certification

16. Survivor Package: Compensation Letter
17. Survivor Package: Attachment 1: Certification of Status for Death Benefit – Standard Calculation
18. Survivor Package: Attachment 2: Certification of Status for Death Benefit – Alternative Calculation
19. Survivor Package: Attachment 3: Death Benefit Certification of Relationship
20. Certification Regarding Medical Records
21. Request for Benefits Form – Spanish
22. Request for Benefits Instructions – Spanish
23. Authorization for Use or Disclosure of Health Information Form – Spanish
24. Authorization for Use or Disclosure of Health Information Instructions – Spanish