information to Docket No. FDA–2008–D–0150. The labeling submission should reference the submission to the docket. We estimate that no more than one submission to the docket will be made annually from one company, and that each submission will take approximately 10 hours to prepare and submit. Recommendations for the CLINICAL STUDIES section of the Full Prescribing Information of the labeling are covered by FDA regulations at §§ 201.56 and 201.57 (21 CFR 201.56 and 201.57) and require such labeling. The information collection associated with these regulations is approved under OMB control number 0910–0572.

2. Section VI.B of the guidance requests that the format of the cardiovascular outcome claim submitted to FDA in a prior approval supplement include the following information:

- A statement that the submission is a cardiovascular outcome claim supplement, with reference to the guidance and related Docket No. FDA–2008–D–0150
- Applicable FDA forms (*e.g.,* 356h, 3397)
- Detailed table of contents
- Revised labeling to include:
  - Draft revised labeling conforming to the requirements in §§ 201.56 and 201.57, and
  - Marked-up copy of the latest approved labeling, showing all additions and deletions, with annotations of where supporting data (if applicable) are located in the submission.

We estimate that on average, 4 cardiovascular outcome claim supplements will be submitted annually from 4 different companies, and that each supplement will take approximately 20 hours to prepare and submit. The guidance also recommends that other labeling changes (*e.g.,* the addition of adverse event data) should be minimized and provided in separate supplements, and that the revision of labeling to conform to §§ 201.56 and 201.57 may require substantial revision to the ADVERSE REACTIONS or other labeling sections.

3. Section VI.C of the guidance states that applicants are encouraged to include the following statement in the drug's promotional materials:

- ''[DRUGNAME] reduces blood pressure, which reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Controlling high blood pressure should be part of comprehensive cardiovascular risk management, including, as appropriate, lipid control, diabetes management, antithrombotic therapy, smoking cessation, exercise, and limited sodium intake. Many patients will require more than one drug to achieve blood pressure goals.''

The inclusion of this statement in the promotional materials for the drug is exempt from OMB review under 5 CFR 1320.3(c)(2).

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Submission to Docket No. FDA–2008–D–0150	1	1	1	10	10
Cardiovascular Outcome Claim Supplement Submission	4	1	4	20	80
Total					90

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimate for the information collection reflects an overall increase of burden. This increase corresponds to an increase in submissions we have received over the last few years.

Dated: July 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15101 Filed 7–15–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0334—Extension]

Agency Information Collection Activities: Proposed Collection: Comment Request; Information Collection Request Title: Countermeasures Injury Compensation Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than September 16, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title, below, for reference.

Information Collection Request Title: Countermeasures Injury Compensation Program, OMB No. 0915–0334—Extension.

Abstract: This is a request for continued OMB approval of the

information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). The CICP, within the Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, administers this compensation program as specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act).

The Secretary of the Department of HHS (Secretary) can issue a PREP Act declaration. When issued, the purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. The Secretary's declaration may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures (*e.g.,* anthrax vaccine) to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration.

Need and Proposed Use of the Information: The CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration or to their estates and/or to certain survivors.

To determine whether a requester is eligible for Program benefits (compensation) for a countermeasure injury, the CICP staff must review the Request for Benefits Package (RFB) that includes the following:

(1) *Request for Benefits Form and Supporting Documentation:* The Request for Benefits Form and supporting documentation initiates the CICP claims review process. They also serve as the CICP's mechanism for gathering required information about the requester, documenting the use or administration of a countermeasure, and obtaining medical information about the countermeasure recipient.

(2) *Authorization for Use or Disclosure of Health Information Form (Authorization Form):* The requestor completes the Authorization Form and gives medical providers permission to disclose the countermeasure recipient's health information via medical records to the CICP for determining eligibility for CICP benefits.

(3) *Additional Documentation and Certification:* During the eligibility review, the CICP provides requesters with the opportunity to supplement their RFB with additional medical records and supporting documentation before the Program makes a final decision. The CICP asks requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case. After the CICP makes a final decision on a case, there are no other opportunities for a requester to submit additional medical records or supporting documents.

(4) *Benefits Package and Supporting Documentation:* A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive payment for unreimbursed medical expenses and/or lost employment income accrued prior to the injured countermeasure recipient's death. These documents ask the requester to submit documentation of the countermeasure recipient's unreimbursed medical expenses and lost employment income. If death was the result of the administration or use of the countermeasure, certain survivor(s) of eligible deceased countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits (42 CFR 110.33). These documents request additional information, such as a marriage license, from the requester to prove that they are a survivor of the deceased countermeasure recipient.

The RFB that the CICP sends to requesters who may be eligible for compensation includes certification forms and instructions outlining the supporting documentation needed to determine the types and amounts of benefits. This documentation is required under 42 CFR 110.60–110.63 of the CICP's implementing regulation to enable the Program to determine the types and amounts of benefits the requester may be eligible to receive.

Likely Respondents: Countermeasure recipients are the most likely respondents to this **Federal Register** notice regarding the CICP information collection request because the CICP reviews, and if eligible compensates, countermeasure recipient injury claims.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUAL BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Request for Benefits Form and Supporting Documentation	100	1	100	11.00	1,100.00
Authorization for Use or Disclosure of Health Information Form	100	1	100	2.00	200.00
Additional Documentation and Certification	30	1	30	.75	22.50
Benefits Package and Supporting Documentation	30	1	30	.13	3.75
Total	260		260		1,326.25

Maria G. Button,

Director, Division of the Executive Secretariat.

[FR Doc. 2019–15007 Filed 7–15–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1902–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—April Through June 2019

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from April through June 2019. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jason Green, by telephone at (571) 777–2723, or by email at *jason.green@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization determination, coverage determination, and at-risk determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an Independent Review Entity (IRE) for Part C organization determination appeals, or by PDPSs and an IRE for Part D coverage determination and at-risk determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges and attorney adjudicators. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council (Council). In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. To help ensure nationwide consistency in that effort, OMHA established a manual, the OCPM. Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations and at-risk determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that the Secretary publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every three months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the three-month period of April through June 2019. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

IV. OCPM Releases for April Through June 2019

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of OCPM provisions that were issued or revised in the three-month period of April through June 2019. This information is available on our website at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

OCPM Chapter 11: Procedural Review and Determinations

This newly issued chapter describes how to conduct a procedural review of an appeal, and how to resolve any identified procedural defects. The procedural review is required to ensure that a request for hearing or review of dismissal meets jurisdictional and filing