



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval;

Public Comment Request; Mpox Vaccine Distribution Request Forms, OMB No. 0915-xxxx

- New

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443-3093.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Mpox Vaccine Distribution Request Forms, OMB

No. 0915-xxxx – New

Abstract: On August 4, 2022, the mpox outbreak was declared a public health emergency (PHE) in the United States. From the outset, HRSA engaged with federal partners across HHS to provide resources to combat the spread of mpox; assist health care providers who are treating people who have mpox; and ensure those who are most at risk are the focus of vaccine response efforts.

HHS authorized HRSA to receive allotments of the JYNNEOS vaccine for mpox for rapid distribution to Ryan White HIV/AIDS Program (RWHAP) recipients. HRSA was identified as a distribution partner due to the health care services provided to individuals with HIV and the number of uninsured and underinsured persons seen in RWHAP and Health Center Programs. The allotments were meant to supplement, not replace, vaccine efforts at jurisdictional levels.

To expedite dispensing of the vaccine, HRSA provided the vaccine to dually funded RWHAP Part C and Health Center providers that care for at-risk populations. Most of the identified providers already had access to the Health Partner Ordering Portal (HPOP), a system HHS uses to quickly distribute vaccines to HHS health partners. For providers who elected to receive the vaccine but did not have access to HPOP, HRSA registered them in the HPOP system. HRSA made 73 shipments to 57 (53 dually funded and four Part C only) RWHAP recipients who elected to receive and distribute the mpox vaccine.

RWHAP recipients that receive shipments of the JYNNEOS vaccine are required to upload administration and inventory/wastage data into HPOP on a weekly basis. The information collected includes federal or state PIN, contact, lot number, description, number of vials, expiration date, courses/doses/bottles administered, bottles available, wastage, reason, and date reported.

RWHAP recipients who accept JYNNEOS vaccine from HRSA are also asked to submit data with information necessary for HRSA to assess the quantity of mpox vaccines requested and their distribution status. The information collected includes grant number; recipient name, point of contact, and phone number; shipping address; shipping point of contact, email address, and phone number; and number of boxes of mpox vaccine requested.

As a result of the PHE for mpox, the Assistant Secretary for Planning and Evaluation issued a Paperwork Reduction Act waiver for collection of these data. Since the PHE ended on January 31, 2023, HRSA is proposing to continue collecting these data until December 31, 2025. This action will help to improve HRSA's ability to provide additional resources and assistance to RWHAP recipients, which may result in increased prevention of mpox among RWHAP clients.

A 60-day notice was published in the **Federal Register** on May 9, 2023, vol. 88, no. 89, pp. 29909-10. There was one comment received. There are no changes made to the information collection since the comment received is outside the scope of this information request.

Need and Proposed Use of the Information: HRSA will use the information collected to (1) assess and improve its response to the mpox outbreak and (2) improve HRSA's ability to provide resources and assistance to RWHAP recipients in future public health emergencies.

Likely Respondents: Dually funded RWHAP Part C and Health Center recipients who accepted at least one shipment of mpox vaccine from HRSA.

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 Annualized Burden Hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Vaccine Distribution Report	57	1	57	0.20	11.40
Wastage Upload Report	57	52	2,964	0.23	681.72
Therapeutic Courses (Administered and Available)	57	52	2,964	0.23	681.72
Total	171				1,374.84

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