

Supporting Statement

Ryan White HIV/AIDS Program Mpox Vaccine Distribution

OMB Control No. 0915-XXXX - New

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting approval from the Office of Management and Budget (OMB) for the continuation of the mpox vaccine distribution data collection instrument that received OMB approval under emergency review on October 17, 2022, with an expiration date of January 31, 2023.

The Department of Health and Human Services (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.

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 the 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.

RWHAP recipients that received shipments of the JYNNEOS vaccine because of the mpox public health emergency (PHE) 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 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, phone number; shipping address; shipping point of contact, email address, and number of boxes of mpox vaccine requested.

Data collection is authorized under Public Law 111 – 352, Section 4 (Government Performance and Results Act (GPRA) Modernization Act of 2010).

2. Purpose and Use of Information Collection

The major purpose of this data collection is 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.

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.

3. Use of Improved Information Technology and Burden Reduction

RWHAP recipients that receive shipments of the JYNNEOS vaccine upload administration and inventory/wastage data into HPOP.

4. Efforts to Identify Duplication and Use of Similar Information

Data that describe the activities of the JYNNEOS recipients are not available elsewhere.

5. Impact on Small Businesses or Other Small Entities

This data collection does not involve small businesses and does not have a significant impact on small entities.

6. Consequences of Collecting the Information Less Frequently

The public health emergency ended on January 31, 2023. HRSA is proposing to continue collecting these data until the end of 2025. Without the weekly reporting of the mpox vaccine distribution, HRSA HIV/AIDS Bureau (HAB) would not be able to:

1. Track and assess mpox vaccine distributed to RWHAP Part C dually funded recipients
2. Assess therapeutic outcomes for the clients of recipients who administered the mpox vaccine
3. Monitor the proper elimination and removal of JYNNEOS vaccine wastage

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

These data will be collected in a manner consistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A:

A 60-day *Federal Register* Notice was published in the Federal Register on May 9, 2023 (Volume 88, No. 89, pages 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.

Section 8B:

In determining the burden estimate and the clarity of the information requested in the report from recipients, HRSA HAB consulted with seven (7) RWHAP Part C dually funded recipients in May 2023. All the recipients in the pilot group reported no issues with the data collection instruments or the data collection process.

9. Explanation of any Payment/Gift to Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality Provided to Respondents

Only summary data will be included in any reports developed from the collection of this information. No individual-level data will be seen by HRSA or any outside party.

11. Justification for Sensitive Questions

Data are reported on the number of people with HIV; however, data submitted to HRSA do not include any client-level data or client-identifying information.

12. Estimates of Annualized Hour and Cost Burden

The estimated annual burden to complete the mpox forms is as follows:

12A. Estimated Annualized Burden Hours

To determine the updated burden estimates, HRSA HAB contacted seven (7) Dually funded RWHAP Part C recipients in May 2023, to determine the amount of time they spend, weekly, to upload the vaccine administration and inventory/wastage data. The revised burden hour table is an adjustment of the burden estimate submitted in the 60-Day *Federal Register* notice publication.

Below is the table illustrating the burden estimates.

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		5,985		1,374.84*

* 1,374.84 hours rounds up to 1,375 hours in ROCIS.

12B. Estimated Annualized Burden Costs

In most cases, healthcare facilities across the country use Registered Nurses to administer and dispose of mpox vaccine waste byproducts. Therefore, the BLS code used for this calculation is 29-1141. The mean hourly rate is used, as opposed to adjusting for locality, since award recipients are spread across the country. The hourly wage rate is doubled to account for overhead costs.

Type of Respondent	Total Burden Hours	Hourly Wage Rate (x2)	Total Respondent Costs**
Vaccine Distribution Report	11.4	85.60	975.84
Wastage Upload Report	681.72	85.60	58,355.23
Therapeutic Courses (Administered and Available)	681.72	85.60	58,355.23
Total			117,686.30

*<https://www.bls.gov/oes/current/oes291141.htm>

** Hourly wage of 42.80 doubled to account for overhead costs.

13. Estimates of Annualized Cost Burden to Respondents or Recordkeepers/Capital Costs

There is no capital or startup costs for this activity. There are no direct costs to respondents other than their time in participating in the data collection, which is shown in the table above.

14. Annualized Cost to Federal Government

Government personnel requires 10 percent time of 1 FTE at a GS-13 step 1 (\$112,015) to provide technical assistance and data analysis support. The wage is adjusted for the Washington-Baltimore-Arlington, DC-MD-VA-WV-PA locality and doubled to account for overhead costs. The total estimated annual cost is approximately \$22,403.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation, Publication, and Project Time Schedule

RWHAP recipients that receive shipments of the JYNNEOS vaccine are required to upload administration and inventory/wastage data into HPOP on a weekly basis.

There are no plans for formal publication of the information.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

This information collection fully complies with the guidelines in 5 CFR 1320.9. The necessary certifications are included in the package.