

SUPPORTING STATEMENT

Health Center COVID-19 Vaccine Program

0906-0062 Revision

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA) is requesting approval from the Office of Management and Budget (OMB) for a revision to the Health Center COVID-19 Vaccine Program information collection request.

The program is part of a White House Initiative to ensure our nation's underserved communities and those disproportionately affected by COVID-19 are equitably vaccinated against COVID-19. In a collaboration between HRSA and the Centers for Disease Control and Prevention (CDC), this program directly allocated COVID-19 vaccines to HRSA-funded health centers the week of February 15, 2021.

This information collection request is to support the implementation of COVID-19 relief funding and response activities and includes forms previously submitted in an emergency information collection request: 1) Health Center COVID-19 Data Collection Survey Tool, 2) Addendum to COVID-19 Data Collection Survey Tool, and 3) the Health Center COVID-19 Vaccine Program Readiness Assessment Tool. HRSA will use the information collected through the tools to better understand health center capacity to provide vaccinations and meet program expectations, technical assistance needs and progress in administering vaccination equitably. This revised information collection request also includes two newly added forms: 1) Primary Care Association (PCA) COVID-19 Data Collection Survey Tool¹ and 2) the Health Center COVID-19 Vaccine Program Conditions of Participation Agreement.

Full proposed measures for respondents are presented in Table 1: Proposed Measures for the Health Center COVID-19 Vaccine Program – Readiness Assessment. HRSA will use this information to assess health center COVID-19 vaccine administration capacity (e.g. staff capacity, inventory management, PPE) and inform the development of training and technical assistance resources for health centers and allow HRSA to assess health center capacity to manage inventory and distribution of vaccines, as well as ability to meet program expectations.

¹ The bi-weekly COVID-19 PCA Survey Tool (comprised of six questions) is currently approved under the HHS Secretary's Public Health Emergency Authority to waive the requirements of the Paperwork Reduction Act during the Public Health Emergency for reporting on a voluntary basis.

Table 1. Proposed Measures for the Health Center COVID-19 Vaccine Program – Readiness Assessment

Measure	Frequency	Expected Number of Responses per Measure per Organization
1. COVID-19 vaccine storage and administration capacity	Once	1
2. Currently receiving COVID-19 vaccines from state	Once	1
3. COVID-19 vaccine capacity and details	Once	12 responses per site
4. Current data reporting on COVID-19 vaccine administration and outcomes	Once	1-6
5. Existence of standing meetings with state/local health department for discussing vaccine administration	Once	1
6. Existence of a vaccine coordinator and back-up	Once	1
7. Existence of scheduling/management process for COVID-19 vaccine appointments and reminders	Once	1 or 2
8. Existence of an effective system for COVID-19 vaccine inventory management and distribution of vaccines to service delivery sites	Once	1
9. Existence of vaccine transportation plan if vaccines need to be relocated	Once	1

Table 2. Proposed Measures for the COVID-19 Data Collection Survey Tool

Measure	Frequency	Expected Number of Responses per Measure per Organization
Bi-Biweekly COVID-19 Survey Questions for All Responding Health Centers		
1. Email address	Biweekly	1
2. State/territory	Biweekly	1
3. Health Center name	Biweekly	1
4. COVID-19 testing capacity	Biweekly	1
5. COVID-19 walk-up/drive-up testing capacity	Biweekly	1
6. Turnaround time for COVID-19 test results	Biweekly	1
7. Number of patients tested for COVID-19, by race and ethnicity	Biweekly	17
8. Number of patients tested positive for COVID-19, by race and ethnicity	Biweekly	17
9. Number of staff positive for COVID-19 in last week	Biweekly	1
10. Percent of staff unable to work	Biweekly	1
11. Number of health center sites closed	Biweekly	1
12. Number of visits last week vs pre-COVID	Biweekly	1
13. Percent of visits conducted virtually last week	Biweekly	1
14. Duration supply of PPE will last, by type of PPE	Biweekly	5
15. Staff received 1 st COVID vaccine dose last week	Biweekly	1
16. Staff received 2 nd COVID vaccine dose last week	Biweekly	1
17. Number of patients received 1 st COVID vaccine dose, by race and ethnicity	Biweekly	17

18. Number of patients received 2 nd COVID vaccine dose, by race and ethnicity	Biweekly	17
19. Challenges deploying COVID-19 vaccine	Biweekly	6
20. Additional comments	Biweekly	1
Biweekly COVID-19 Survey Supplemental Questions for ONLY Health Centers Participating in the Health Center COVID-19 Vaccine Program (Addendum)		
*To include vaccine data <i>only</i> on vaccines given from the Health Center COVID-19 Vaccine Program allocation		
1. Staff received 1 st COVID vaccine dose last week	Biweekly	1
2. Staff received 2 nd COVID vaccine dose last week	Biweekly	1
3. Number of patients received 1 st COVID vaccine dose, by special populations	Biweekly	4
4. Number of patients received 2 nd COVID vaccine dose, by special populations	Biweekly	4
5. If all vaccine doses received were administered	Biweekly	1
6. Number of vaccine doses needed	Biweekly	1
7. Additional comments on COVID-19 vaccine distribution	Biweekly	1

The data will allow HRSA to assess health center capacity prior to program enrollment, supporting successful vaccine allocation strategies, while providing HRSA with information on the effectiveness of vaccine distribution through this program and to inform HRSA in resource allocation and technical assistance to health centers. These data collection tools are essential for HRSA’s ability to assess the readiness and interest of HRSA-funded health centers preliminarily identified by the Centers for Disease Control and Prevention (CDC) and HRSA to receive a direct allocation of a limited supply of COVID-19 vaccines, and enable progress towards the White House Initiative’s goals in health equity.

The two additional forms will collect the following information:

Measure	Frequency	Expected Number of Responses per Measure per Organization
HRSA Health Center COVID-19 Vaccine Program Conditions of Participation Agreement		
1. Health center legal name	Once	1
2. Health Center Program grant or look-alike number	Once	1
3. Health Center telephone number	Once	1
4. Email	Once	1
5. Health Center address	Once	1
6. Name of Authorized Representative	Once	1
7. Title/Position	Once	1
8. Email	Once	1
9. Phone Number	Once	1
10. Date	Once	1
11. Signature	Once	1

Measure	Frequency	Expected Number of
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		Responses per Measure per Organization
Survey Tool Questions for PCAs		
1. Email address	Monthly	1
2. Organization name	Monthly	1
3. Key State-wide Issues/Concerns: Top five <ul style="list-style-type: none"> • PPE supplies • Testing supplies • Financial stability • Infrastructure needs (such as technology or equipment to support operations) • Care for specific populations • Addressing health disparities • Telehealth/virtual health care • Workforce • COVID-19 vaccine distribution and administration • Other (e.g., emerging issues) 	Once	5
4. How is your organization connected with your state/local emergency response efforts (e.g., public health department, governor’s office), including testing, reopening plans, vaccination plans, etc.? Please include any changes since your last update	Once	1
5. Are there issues with COVID-19 vaccine confidence, communications, or outreach in your state? If yes, please identify the specific counties (or other local public health jurisdictions) and describe the circumstances.	Once	1
6. Please provide any additional COVID-19 related information, comments, and/or needs from HRSA.	Once	1

2. Purpose and Use of Information

The readiness assessment will support HRSA’s analysis of health center ability to successfully participate in the Health Center COVID-19 Vaccine Program. These data are critical to determine health center capacity to implement the vaccination program as well as comply with program requirements. These data will be used to assess program readiness including:

- Ability to safely store the vaccine
- Availability of trained and credentialed staff and other staff capacity
- Reporting capacity
- Sufficient PPE
- Plan for vaccine transport

The biweekly survey and addendum will support HRSA's ability to monitor progress towards program goals and ensure appropriate vaccine administration as well as better understand training and technical assistance, funding, and other health center resource needs. The Conditions of Participation will ensure HRSA requirements for participation in the HRSA Health Center COVID-19 Vaccine Program are met by health centers, and the PCA survey tool will inform HRSA's ability to monitor state and regional progress and challenges encountered by training and technical assistance providers.

3. Use of Improved Information Technology

To complete the readiness assessment and Conditions of Participation, select health center staff will log into the Health Center COVID-19 Vaccine Program Online Community using a user name and password. The user name will be the email address and a new password will be established during the initial log in. All health centers supported by the Bureau of Primary Health Care are preloaded into the Salesforce CRM. New health centers will be verified using the Electronic Handbooks system of record, then updated in Salesforce by a System Administrator. All users are required to select their health center when submitting the readiness assessment. These tools will be used to collect only the minimum information necessary for the purposes of program readiness and implementation assessment.

To complete the biweekly COVID-19 Data Collection Survey Tool and addendum, and Survey Tool Questions for PCAs, health centers and PCA points of contacts will only need to complete the Salesforce form, no log in is required.

4. Efforts to Identify Duplication

Data required to evaluate vaccine program readiness and monitor progress, such as information on staff and reporting capacity, vaccine administration, and number of people vaccinated by special population type are not available elsewhere. HRSA is in constant communication with CDC in order to avoid overlap with other reporting systems. As HRSA is the administrator for this federal allocation program, these HRSA tools are essential and non-duplicative to support ongoing and monitoring for program implementation.

5. Involvement of Small Entities

The information being requested has been held to the absolute minimum required for the intended use of the data.

6. Consequences if Information Collected Less Frequently

HRSA will contact prospective health centers about participating in the Health Center COVID-19 Vaccine Program. It is imperative that these health centers quickly complete the Readiness Assessment to support HRSA's analysis of health center ability to successfully participate in the program.

Currently, health centers voluntarily complete the biweekly COVID-19 Data Collection Survey Tool, which HRSA has been using to collect key information from health centers regarding COVID-19 activities to assist in tracking health center capacity and the impact of COVID-19 public health emergency on health center operations, patients, and staff. Vaccine program participants will complete the COVID-19 Data Collection Survey Tool and Addendum on a biweekly basis in order for HRSA to oversee the appropriate biweekly

shipments of vaccine and align with health centers' ability to administer vaccine. Because of the urgent nature of the COVID-19 pandemic response, HRSA will require biweekly program data to ensure program integrity, effective and equitable vaccine allocations, and provide technical assistance in a timely manner. Biweekly reporting is necessary to determine whether the program is on track to achieve White House goals.

7. Consistency with Guidelines in 5 CFR 1320.5(d)(2)

The data will be collected in a manner fully consistent with the guidelines in 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

A 60-day Federal Register Notice was published in the Federal Register on April 23, 2021, vol. 86, No. 77; pp. 21756-57. There were no public comments.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The tools do not require any information that could identify individual patients. Aggregate data on the number of patients who received services will be collected, but client names or other personally identifiable information will not be collected.

11. Questions of a Sensitive Nature

The tools do not collect confidential or protected information. There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

These Readiness Assessment, Conditions of Participation, Survey Questions for PCAs and COVID-19 Data Collection Survey and Addendum tools will be used to collect the minimum data necessary to monitor and support successful vaccination strategies for the Health Center COVID-19 Vaccination Program. The Readiness Assessment Tool, Conditions of Participation, and COVID-19 Data Collection Survey and Addendum are only required for health centers who voluntarily choose to participate in the program. The Survey Questions for PCAs are recommended for PCA response and not required.

Burden estimates for respondents are presented in Table 2: Estimated Burden of Responses over the Entire Reporting Period. The total estimated burden for health center respondents is 101,342.25 hours per year. To assess the burden, HRSA OQI gathered data on the anticipated number of respondents and responses based on internal data and assessed average burden hours based on input gathered from health centers currently completing the voluntary biweekly survey. More accurate estimates will be collected and reported once they are available.

Table 2. Estimated Annual Burden of Responses

Form Name	Number of Respondents	Number of Responses to Form per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Condition of Participation Agreement (one-time completion for vaccine program participants only)	1,467 (Total health centers, including look-alikes, in 2019)	1	1,467	.25	366.75
Readiness Assessment Tool (one-time completion for vaccine program participants only)	1,467 (Total health centers, including look-alikes, in 2019)	1	1,467	.5	733.5
Health Center COVID-19 Data Collection Survey Tool (weekly completion of existing 20 questions)	1,389 (Total health centers in 2019)	48	66,672	1	66,672
Addendum to COVID-19 Data Collection Survey Tool (weekly completion for vaccine program participants only)	1,389 (Total health centers in 2019)	48	66,672	.5	33,336
PCA COVID-19 Data Collection Survey Tool (bi-weekly completion of existing six questions)	52	6	312	.75	234
Total	5,764		136,590		101,342.25

13. Estimates of Annualized Cost Burden to Respondents

Table 3: Estimated Annualized Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Clinic Managers	101,342.25	\$63.12	\$6,396,722.82

Wages of health care office managers average \$48.55 according to 2019 Occupational Employment Statistics from the U.S. Bureau of Labor Statistics (BLS)². Benefits and fringe are estimated as 30% of the hourly cost or \$14.57 per hour. The total hourly cost of clinic managers is therefore estimated as \$63.12 per hour composed of \$48.55 + \$14.57.

14. Estimated Cost to the Federal Government

HRSA has funded a firm fixed price contract with Deloitte Consulting for Salesforce services and technical assistance. As part of the contract, Deloitte is required to develop, maintain, and promote the effective use and adoption of Salesforce as a full Customer Relationship Management system that increases BPHC’s ability to support the Health Center Program and respond quickly to national crises. The cost of these services is \$486,047 for a 12-month support period. There are no costs specific to these two tools outside the general contracts for technical support and software licenses.

The estimated annual cost to the government for contracts providing technical assistance, training and data reporting support, data processing, editing, and verification is \$1 million. Additionally, the estimated annual cost to the government for FTE is \$58,595 (1 GS-14 – approximately 50% time of work) for reviewing and managing the contract. Total estimated annual costs to the government are \$1.5 million.

15. Changes in Burden

The newly added forms account for the increase in the proposed burden. The existing COVID-19 Data Collection Survey Tool will change in status from voluntary to mandatory for Health Center COVID-19 Vaccination Program participants. Specifically, Health Center COVID-19 Vaccination Program participants will be required to: 1) Complete the Readiness Assessment Tool once, and 2) upon acceptance to the program, complete the biweekly COVID-19 Data Collection Survey Tool and Addendum throughout the duration of program participation.

16. Time Schedule, Publication and Analysis Plans

HRSA will work with interested HRSA-supported health centers to complete the one-time readiness assessment.

² Occupational Employment Statistics. U.S. Bureau of Labor Statistics. Occupational Employment and Wages, May 2019: 11-9111 Medical and Health Services Managers. <https://www.bls.gov/oes/current/oes119111.htm>

The biweekly survey opens on Fridays and closes on Tuesdays, and health centers report on their experience for the time period beginning the prior Saturday through that Friday. HRSA reviews biweekly data on an ongoing basis, within 7 days of the survey close day, and will conduct ongoing analyses on special populations pertaining to the White House Initiative goals. Health Center COVID-19 Vaccine Program participants will complete the biweekly COVID-19 Data Collection Survey and Addendum throughout the duration of program participation. HRSA anticipates administering the Health Center COVID-19 Vaccine Program until it is no longer needed.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This project fully complies with 5 CFR 1320.9.