

## SUPPORTING STATEMENT

### **Health Center COVID-19 Vaccine Program Readiness Assessment and COVID-19 Data Collection Survey Tool with Addendum for the Health Center COVID-19 Vaccine Program**

#### **Emergency Clearance Request**

#### **A. Justification**

##### **1. Circumstances of Information Collection**

The Health Resources and Services Administration (HRSA) is requesting an expedited review from the Office of Management and Budget (OMB) for 1) two new data collection tools to support the Health Center COVID-19 Vaccine Program, and 2) approval of the existing COVID-19 Data Collection Survey Tool.<sup>1</sup> The program is part of a White House Initiative with the goal of administering 100 million shots in 100 days, with a focus on equity. In a collaboration between HRSA and the Centers for Disease Control and Prevention (CDC), this program will directly allocate a limited supply of COVID-19 vaccines to select HRSA-funded health centers starting the week of February 15, 2021.

HRSA is proposing a new readiness assessment – the Health Center COVID-19 Vaccine Program Readiness Assessment – a one-time tool to collect data on the readiness and interest of HRSA-funded health centers preliminarily identified by CDC and HRSA to receive a direct allocation of a limited supply of COVID-19 vaccines.

Currently, HRSA-funded health centers and Look-Alikes voluntarily complete the weekly COVID-19 Data Collection Survey Tool. HRSA proposes an addendum to the weekly COVID-19 Data Collection Survey Tool to help track vaccine administration and progress for health center participating in the Health Center COVID-19 Vaccine Program.

HRSA proposes mandatory data collection from health centers participating in the vaccine allocation program via these three instruments: 1) the new Readiness Assessment Tool, 2) the existing COVID-19 Data Collection Survey Tool, and 3) the new Addendum to COVID-19 Data Collection Survey 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.

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<sup>1</sup> The weekly COVID-19 Data Collection Survey Tool (currently comprised of 20 questions) is currently approved under the HHS Secretary's Public Health Emergency Authority to waive the requirements of the Paperwork Reduction during the Public Health Emergency for reporting on a voluntary basis.

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.

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

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

Because of the urgent nature of the COVID-19 pandemic response and need to support a life-saving vaccination rollout through this White House Initiative, it is critical for HRSA to obtain health center capacity and implementation data as quickly as possible through these mechanisms. 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.

## **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 weekly 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.

### **3. Use of Improved Information Technology**

To complete the readiness assessment, selected 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 weekly COVID-19 Data Collection Survey Tool and addendum, health centers 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 weekly 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 weekly basis in order for HRSA to oversee the appropriate weekly 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 weekly program data to ensure program integrity, effective and equitable vaccine allocations, and provide technical assistance in a timely manner. Weekly 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**

Due to the urgent nature of this request, there was not time for a public comment period.

HRSA worked in partnership with CDC to develop this program, including consultations on the information necessary to collect from health centers to manage this program.

#### **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 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 and COVID-19 Data Collection Survey and Addendum are only required for health centers who voluntarily choose to participate in the program.

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 100,690 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 weekly survey. More accurate estimates will be collected and reported once they are available.

**Table 2. Estimated Annual Burden of Responses**

<b>Form Name</b>	<b>Number of Respondents</b>	<b>Number of Responses to Form per Respondent</b>	<b>Total Responses</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Readiness Assessment Tool (one-time completion for vaccine program participants only)	1,364 (Total health centers in 2019 minus the 25 health centers that complete the Readiness Assessment directly with HRSA)	1	1,364	.5	682
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
<b>Total</b>	<b>4,142</b>		<b>134,708</b>		<b>100,690</b>

### 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	100,690	\$63.12	\$6,355,552.80

Wages of health care office managers average \$48.55 according to 2019 Occupational Employment Statistics from the U.S. Bureau of Labor Statistics (BLS)<sup>2</sup>. 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 Readiness Assessment and the Addendum to the COVID-19 Data Collection Survey Tool are new data collection instruments. 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 weekly COVID-19 Data Collection Survey Tool and Addendum throughout the duration of program participation.

### 16. Time Schedule, Publication and Analysis Plans

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<sup>2</sup> 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>



HRSA will work with a subset of 250 health centers to complete the one-time readiness assessment in the next two to three weeks and will continue to encourage other interested health centers to complete the readiness assessment tool as quickly as possible.

The weekly 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 weekly 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 weekly 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.