



TO: Sharon Block, Associate Administrator
Office of Information and Regulatory Affairs

FROM: Diana Espinosa, Acting Administrator

DATE: February 16, 2021

SUBJECT: Expedited Review of the Health Center COVID-19 Vaccine Program Readiness Assessment and the COVID-19 Data Collection Survey Tool with Addendum for the Health Center COVID-19 Vaccine Program

ISSUE

The Health Resources and Services Administration (HRSA) is requesting an expedited review of: (1) The Health Center COVID-19 Vaccine Program Readiness Assessment, and (2) The COVID-19 Data Collection Survey Tool, with Addendum questions for health centers participating in the Vaccine Program. These data collection tools were developed by HRSA to support implementation of the Health Center COVID-19 Vaccine Program and improve HRSA's ability to provide resources and technical assistance to health centers and strengthen the federal response to the COVID-19 pandemic. These data collection tools are essential for HRSA's ability to assess: (1) 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 (2) progress in vaccine administration and equitable access to vaccine.

BACKGROUND

President Biden announced the Administration's goal of administering 100 million shots in 100 days and ensuring that vaccines are administered equitably. Through collaboration between HRSA and CDC, the Health Center COVID-19 Vaccine Program will directly allocate a limited supply of COVID-19 vaccines to select HRSA-funded health centers starting the week of February 15, 2021.

The Health Center COVID-19 Vaccine Program Readiness Assessment Tool is necessary to document and assess health center COVID-19 vaccine administration capacity (e.g. capacity to safely store the vaccine, availability of trained and credentialed staff and sufficient PPE to administer vaccine in a timely manner, and reporting capacity, including to state and/or local departments of health). The tool also includes an assessment of health center capacity to manage inventory and distribution of vaccines, as well as ability to meet program expectations. This tool serves as the designated mechanism for health centers to propose sites for vaccine delivery.

Currently, HRSA-funded health centers and Health Center Program look-alikes voluntarily

complete the weekly COVID-19 Data Collection Survey Tool.¹ HRSA uses this tool to collect key information regarding COVID-19 activities to assist in tracking health center capacity and the impact of the COVID-19 public health emergency on health center operations, patients, and staff, as well as to better understand training and technical assistance, funding, and other health center resource needs. HRSA requires a mechanism to capture data on vaccine doses administered by health centers participating in the Health Center COVID-19 Vaccine Program. As a result we are adding an Addendum to the Survey Tool to capture this additional information.

Given the critical need to provide vaccines in a timely and equitable manner, and that no existing data collection system currently captures the information contained in the proposed Readiness Assessment Tool and Addendum to COVID-19 Data Collection Survey Tool, HRSA needs to move expeditiously to establish a mechanism to assess health center readiness for this initiative and implement it.

HRSA proposes mandatory data collection from health centers participating in the vaccine allocation program via 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.

DISCUSSION

Health Center COVID-19 Vaccine Program Readiness Assessment Tool

Health centers who wish to participate in the vaccine program will be required to complete the Health Center COVID-19 Vaccine Program Readiness Assessment Tool. This one-time assessment is comprised of a total of 10 questions, including 9 yes or no questions and 1 multiple choice question, with 3 questions possibly requiring a written response. Health centers will securely complete the Readiness Assessment Tool in the Health Center COVID-19 Vaccine Program Online Community.

The Readiness Assessment Tool will be open in the Health Center COVID-19 Vaccine Program Online Community on Monday, February 15, 2021. Information provided via the Readiness Assessment tool will support HRSA assessment of the health center's capacity to administer vaccines and meet program expectations, inform the development of training and technical assistance resources for health centers, and support the establishment of a federal vaccine program account.

COVID-19 Data Collection Survey Tool and Addendum

Health centers selected for program participation will also be required to complete the weekly COVID-19 Data Collection Survey Tool (currently comprised of 20 questions) as well as additional questions in the survey addendum through the Health Center COVID-19 Vaccine Program Online Community (<https://hrsa.force.com/HRSAAPHC/s/health-center-survey>) to support secure data collection.

¹ The weekly survey 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.

Approval of the Readiness Assessment Tool and the COVID-19 Data Collection Survey Tool and Addendum is urgent and time-sensitive to ensure that HRSA and CDC, in coordination with the jurisdictions, can effectively analyze future vaccine allocation, distribution, and uptake data to determine vaccine allocations to health centers and expand participation in this White House initiative.

Because of the urgent nature of the COVID-19 pandemic response and the 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. It will also inform HRSA in resource allocation and technical assistance to health centers.

These data collection instruments will provide HRSA with critical and timely data on health center capacity for program participation.

Thank you for consideration of this expedited approval.

Diana Espinosa

Attachments:
PRA Emergency Clearance Package