

HHS COVID-19 Testing Supply Program Agreement *and*

Updated HRSA COVID-19 Testing Supply Program Conditions of Participation Agreement for Medicare-certified Rural Health Clinics

The Federal Office of Rural Health Policy (FORHP) is administering the COVID-19 Testing Supply Program and N95 Mask Program on behalf of HRSA for Medicare-certified Rural Health Clinics (RHCs).

Eligible applicants include Medicare-certified RHCs and organizations that own and operate Medicare-certified RHCs (Primary Organizations). Eligible organizations wishing to enroll in the HRSA COVID-19 Testing Supply Program and N95 Mask Program must complete the information required in the agreements below and submit the document to RHCTestKits@hrsa.gov.

Organizations that own and operate multiple RHCs should submit one copy of the HHS COVID-19 Testing Supply Program Agreement and HRSA COVID-19 Testing Supply Program Conditions of Participation Agreement that includes the CMS Certification Numbers (CCNs) for all participating RHCs.

1. HHS COVID-19 Testing Supply Program Agreement

| PRIMARY ORGANIZATION/RURAL HEALTH CLINIC (RHC) IDENTIFICATION AND MAIN PROGRAM POINT OF CONTACT | |
|---|---|
| Primary Organization/RHC Name: | |
| Program Point of Contact (POC) Name: | |
| POC direct telephone: | POC Email (<i>must be a monitored account</i>): |

Primary Organization/RHC address:

RURAL HEALTH CLINIC (RHC) IDENTIFICATION & CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) CERTIFICATION NUMBER (CCN)

Organizations that own and operate multiple RHCs should include all participating RHCs and the corresponding CMS Certification Number (CCN). Additional RHCs can be listed on page 4 if applicable.

| RHC Name as listed in QCOR ¹ : | RHC CCN: |
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RESPONSIBLE OFFICER

For the purposes of this Agreement, in addition to Organization/Main Program Point of Contact, the Responsible Officer identified below will be accountable for compliance with the conditions specified in the Agreement.

Chief Executive Officer (or Chief Fiduciary)

| | | |
|------------|-------------|-----------------|
| Last name: | First name: | Middle initial: |
| | | |
| Title: | | |

¹ <https://qcor.cms.gov/main.jsp>

| | |
|-------------------|--------|
| Telephone number: | Email: |
|-------------------|--------|

Address:

AGREEMENT REQUIREMENTS

I understand this is an agreement between the Organization and HHS. To receive COVID-19 testing supplies and N95 masks at no cost for use by patients and the community in which it is located, the Organization agrees that it will adhere to the following requirements:

- | | |
|----|--|
| 1. | Organization must make use of testing supplies in conformance with the Food and Drug Administration’s (FDA) Emergency Use Authorization (EUA) for the specific test kits or point of care testing supplies provided, the EUA Fact Sheet for Health Care Providers, and all other FDA authorized accompanying materials (and as the FDA may revise the EUA and accompanying materials), and consistent with all requirements, recommendations, and other guidance of HHS. |
| 2. | Organization must not sell or seek reimbursement for the testing supplies or N95 masks that the federal government provides at no cost to Organization. |
| 3. | Organization must provide the tests or masks regardless of the recipient’s ability to pay administration or related fees or coverage status. Organization may not seek any reimbursement, including through balance billing, from the test recipient. |
| 4. | Organization must comply with FDA EUA requirements for use of testing supplies and masks, including ensuring that appropriate storage, inventory management and administration methods are in place. |
| 5. | Organization must order supplies available under the HRSA COVID-19 Testing Supply Program and HRSA COVID-19 N95 Mask Program through the HHS-designated systems. Organization must report the number of testing supplies or masks that are in stock, expired, or wasted using the HHS designated diagnostic ordering system. |
| 6. | Organization must comply with all applicable federal, state, local or territorial laws that impact the distribution of self-tests or COVID-19 test administration to patients and within the community. Organization must comply with applicable patient assent or consent laws for administration of COVID-19 tests. |
| 7. | Organization must have processes to ensure timely and proper acceptance of testing supplies or masks. Those processes must include, but are not limited to, procedures for accepting delivery through commercial delivery services. Organization must report any testing supplies or masks that are damaged upon delivery pursuant to the process provided by the delivery service and to HHS within 24 hours. HHS will provide procedures for reporting. |
| 8. | Organization may use contractors to perform some or all of Organization’s duties under Agreement. Organization must ensure that any contractor performs its duties in full compliance with Agreement and Organization is responsible under Agreement for any non-compliance with Agreement by any of its contractors. Furthermore, any knowledge concerning or resulting from performance of Agreement by any of Organization’s contractors is imputed to Organization. |

By registering for the HRSA COVID-19 Testing Supply Program, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling testing supplies and/or N95 masks understand and will comply with Agreement requirements listed above.

Organization is subject to applicable statutes and regulations governing each federal healthcare program and any HHS-sponsored COVID-19 relief program for program- specific conditions. Reimbursement for distributing over the counter tests is not available under any federal healthcare program or any HHS-sponsored COVID-19 relief program.

Non-compliance with the terms of Agreement may result in suspension or termination from the HHS COVID-19 Testing Supply Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, including but not limited to 18 U.S.C. §§ 1001, 1035, 1347, 1349.

HHS may terminate this Agreement with two weeks written notice.

Organization may cease its participation in the HHS COVID-19 Testing Supply Program. To do so, Organization must provide written notice to HHS no later than two weeks before Organization wishes to end its participation. During that period of at least two weeks, Organization must comply with Agreement and Organization will not receive any further deliveries of testing supplies.

Should HHS desire to modify the terms of this Agreement, HHS will provide Organization with at least two weeks written notice of the modified terms. If Organization does not agree with the changes, Organization may withdraw from the agreement with two weeks written notice.

By entering into Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.²

Check the box to agree with the above-stated requirements

² See Pub. L. No. 109-148, Public Health Service Act § 319F-3 and § 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020), and as amended.

2. HRSA COVID-19 Testing Supply Program Conditions of Participation Agreement

HRSA COVID-19 Testing Supply Program Conditions of Participation Agreement

To ensure our nation's underserved communities and those disproportionately affected by COVID-19 have equitable access to COVID-19 tests, the Health Resources and Services Administration (HRSA) in collaboration with the Department of Health and Human Services is facilitating the HRSA COVID-19 Testing Supply Program to directly allocate COVID-19 testing supplies to HRSA-supported health centers to utilize at no cost to their patients and communities.

This HRSA COVID-19 Testing Supply Program Conditions of Participation (COP) Agreement is between the Organization, which is the participating health center, and HRSA. This Program will distribute COVID-19 testing supplies to health centers participating in the HRSA COVID-19 Testing Supply Program at no cost. Participation in this Program does not guarantee continued shipment or any particular number of tests. This agreement shall govern all sites that receive and utilize COVID-19 testing supplies through the HRSA COVID-19 Testing Supply Program. By completing this form, you agree to adhere to each of the stated requirements. Participation in this Program is voluntary and may be terminated at any time and for any reason by the health center or HRSA.

AGREEMENT REQUIREMENTS

To participate in the Program, the Rural Health Clinic agrees to:

- 1) Enrollment in and compliance with the HHS COVID-19 Testing Supply Program Agreement**
 - a. Enroll in the HRSA COVID-19 Testing Supply Program to receive and utilize COVID-19 testing supplies and/or N95 masks at no cost.
 - b. Agree to and comply with requirements in the HHS COVID-19 Testing Supply Program Agreement.
- 2) Accurate completion and approval of the HRSA COVID-19 Testing Supply Program Conditions of Participation and Site Selection**
 - a. Certify that the health center has a policy and procedure for ensuring that staff who receive or utilize the COVID-19 testing supplies and N95 masks comply with all requirements set forth by HHS and HRSA.
 - b. Identify a testing coordinator at each service site who will be responsible for receiving shipments and managing inventory.
 - c. Identify the health center locations to receive the COVID-19 testing supply and N95 masks shipments.
- 3) Data reporting**
 - a. Maintain accurate inventory using the HHS designated diagnostic ordering system.
 - b. Comply with all state, local and federal required data reporting requirements (as applicable).
- 4) Other requirements**
 - a. Ensure timely utilization of all COVID-19 testing supplies and N95 masks received through the Program.

AUTHORIZED ORGANIZATION REPRESENTATIVE

By completing the information below, the Rural Health Clinic agrees to adhere to each of the above-stated requirements. The Rural Health Clinic must complete this agreement to receive COVID-19 testing supplies through the HRSA COVID-19 Testing Supply Program. The Rural Health Clinic or HRSA may terminate this agreement at any time.

Signature of Authorized Representative _____

Name of Authorized Representative _____

Email: _____

Phone Number: _____

Check the box to agree with the above-stated requirements