HRSA COVID-19 Uninsured Program Terms and Conditions – Testing Services

Acceptance of Terms and Conditions

I hereby attest to the following Terms and Conditions on behalf of the provider with the Tax Identification Number associated with this attestation (“Recipient”). I further attest that I am authorized to make such attestation on behalf of the Recipient. The Terms and Conditions below are not an exhaustive list and the Recipient agrees to comply with any other applicable statutes and regulations.

The Recipient plans to submit claims for reimbursement for COVID-19 Testing and/or Testing-Related Items and Services provided to FFCRA Uninsured Individuals (as those terms are further defined below). The Recipient acknowledges that each time the Recipient submits such claims for reimbursement, each claim must be in full compliance with these Terms and Conditions, and submission of those claims confirms the Recipient’s ongoing compliance with these Terms and Conditions.

The Recipient acknowledges that the Recipient’s full compliance with all Terms and Conditions is material to the Secretary’s decision to disburse funds to the Recipient. Non-compliance with any Term or Condition is grounds for the Secretary to recoup some or all of the payments made.

These Terms and Conditions apply directly to the Recipient. In general, the requirements that apply to the Recipient also apply to subrecipients and contractors, unless an exception is specified.

FFCRA Relief Fund Payment Terms and Conditions

- The “Payment” means the funds received from the Public Health and Social Services Emergency Fund, as appropriated in Public Law 116-127 (“FFCRA Relief Fund”) to provide “COVID-19 Testing” and “Testing-Related Items and Services” to “FFCRA Uninsured Individuals,” as those terms are further defined below. The “Recipient” means the healthcare provider, whether an individual or an entity, receiving the Payment.
  - COVID-19 Testing means:
    - An in vitro diagnostic test defined in section 809.3 of title 21, Code of Federal Regulations (or successor regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19, and the administration of such a test, that—
      - Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k), 360c, 360e, 360bbb–3);
      - The developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;
• Is developed in and authorized by a State that has notified the Secretary of Health and Human Services of its intention to review tests intended to diagnose COVID-19; or

• Other test that the Secretary determines appropriate in guidance.

  o Testing-Related Items and Services means items and services furnished to an individual during health care provider office visits (including in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of COVID-19 Testing but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product.

  o FFCRA Uninsured Individuals means individuals who, as of the date of service for which Recipient seeks Payment, are not enrolled in—

    ▪ A Federal health care program (as defined under section 1128B(f) of the Social Security Act (42 U.S.C. 1320a-7b(f)), including an individual who is eligible for medical assistance only because of subsection (a)(10)(A)(ii)(XXIII) of Section 1902 of the Social Security Act; or

    ▪ A group health plan or health insurance coverage offered by a health insurance issuer in the group or individual market (as such terms are defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg-91)), or a health plan offered under chapter 89 of title 5, United States Code.

• The Recipient certifies that it is not currently terminated from participation in Medicare or precluded from receiving payment through Medicare Advantage or Part D; is not currently excluded from participation in Medicare, Medicaid, and other Federal health care programs; and does not currently have Medicare billing privileges revoked.

• The Recipient certifies that it, or its agents, provided the COVID-19 Testing and/or Testing-Related Items and Services on the Recipient’s claim form to the FFCRA Uninsured Individuals identified on the claim form; that the dates of service occurred on February 4, 2020, or later; and that all items and services for which Payment is sought were medically necessary. The Recipient also certifies that to the best of its knowledge, the patients identified on the claim form were FFCRA Uninsured Individuals at the time the services were provided.

• The Recipient certifies that it will not use the Payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse. If the Recipient subsequently receives reimbursement for any items or services for which the Recipient requested Payment from the FFCRA Relief Fund, the Recipient will return to HHS that portion of the Payment which duplicates payment or reimbursement from another source. The Recipient will not include costs for which Payment was received in cost reports or otherwise seek uncompensated care reimbursement through federal or state programs for items or services for which Payment was received.
• The Recipient shall submit reports as the Secretary determines are needed to ensure compliance with conditions that are imposed on this Payment, including all relevant claims data, and such reports shall be in such form, with such content, as specified by the Secretary in future program instructions directed to all Recipients. The Recipient acknowledges and agrees that the Secretary will share relevant claims data with components of the Department of Health and Human Services.

• The Recipient consents to the Department of Health and Human Services publicly disclosing the Payment that Recipient may receive from the FFCRA Relief Fund.

• The Recipient certifies that all information it provides as part of its application for the Payment, as well as all information and reports relating to the Payment that it provides in the future at the request of the Secretary or Inspector General, are true, accurate and complete, to the best of its knowledge. The Recipient acknowledges that any deliberate omission, misrepresentation, or falsification of any information contained in a request for reimbursement or future report may be punishable by criminal, civil, or administrative penalties, including but not limited to revocation of Medicare billing privileges, exclusion from federal health care programs, and/or the imposition of fines, civil damages, and/or imprisonment.

• Not later than 10 days after the end of each calendar quarter, any Recipient that is an entity receiving more than $150,000 total in funds under the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), the Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123), the Families First Coronavirus Response Act (P.L. 116-127), or any other Act primarily making appropriations for the coronavirus response and related activities, shall submit to the Secretary and the Pandemic Response Accountability Committee a report. This report shall contain: the total amount of funds received from HHS under the foregoing enumerated Acts; the amount of funds received that were expended or obligated for each project or activity; a detailed list of all projects or activities for which the funds were expended or obligated, including: the name and description of the project or activity, and the estimated number of jobs created or retained by the project or activity, where applicable; and detailed information on any level of subcontracts or subgrants awarded by the Recipient or its subcontractors or subgrantees, to include the data elements required to comply with the Federal Funding Accountability and Transparency Act of 2006 allowing aggregate reporting on awards below $50,000 or to individuals, as prescribed by the Director of the Office of Management and Budget.

• The Recipient shall maintain appropriate records and documentation including, as applicable, documentation described in 45 CFR § 75.302 – Financial management and 45 CFR § 75.361 through 75.365 – Record Retention and Access, and other information required by future program instructions to substantiate Payments under this award. The Recipient shall promptly submit copies of such records and documentation upon the request of the Secretary, and Recipient agrees to fully cooperate in all audits the Secretary, Inspector General, or Pandemic Response Accountability Committee conducts to ensure compliance with these Terms and Conditions.

• The Recipient agrees that all claims it submits will be full and complete (i.e., no interim bills or corrected claims). The Recipient acknowledges that all payments are final and there will be no adjustments.
• The Secretary will reimburse the Recipient generally at Medicare rates (including any amounts that would have been due to the provider as patient cost sharing) for the COVID-19 Testing and/or Testing-Related Items and Services that Respondent provided to FFCRA Uninsured Individuals for which the Recipient submits claims to the FFCRA Relief Fund. Exclusions from coverage and alternatives to where Medicare rates do not apply are outlined in the program details.

• The Recipient certifies that it will not engage in “balance billing” or charge any type of cost sharing for any COVID-19 Testing and/or Testing-Related Items and Services provided to FFCRA Uninsured Individuals for which the Recipient receives a Payment from the FFCRA Relief Fund. The Recipient shall consider Payment received from the FFCRA Relief Fund to be payment in full for such care or treatment.

• If the Recipient, prior to signing these Terms and Conditions, charged any FFCRA Uninsured Individuals a fee for COVID-19 Testing and/or Testing-Related Items and Services for which the Recipient subsequently received a Payment from the FFCRA Relief Fund, the Recipient will communicate to the FFCRA Uninsured Individuals that they do not owe Recipient any money for that care or treatment. If an FFCRA Uninsured Individual paid the Recipient for any portion of such care or treatment, the Recipient will timely return the payment to the FFCRA Uninsured Individual.

The following statutory provisions also apply:

**General Provisions in FY 2020 Consolidated Appropriation**

**SEC. 202. Executive Pay.** None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.

**SEC. 210. Funding Prohibition for Gun Control Advocacy.** None of the funds made available in this title may be used, in whole or in part, to advocate or promote gun control.

**SEC. 503. Lobbying**

(a) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any State or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any State or local government, except in presentation to the executive branch of any State or local government itself.

(b) No part of any appropriation contained in this Act or transferred pursuant to section 4002 of Public Law 111–148 shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the
enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any State government, State legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a State, local or tribal government in policymaking and administrative processes within the executive branch of that government.

(c) The prohibitions in subsections (a) and (b) shall include any activity to advocate or promote any proposed, pending or future Federal, State or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including but not limited to the advocacy or promotion of gun control.

SEC. 506. Prohibits Use of Federal Funds for Abortions.

(a) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for any abortion.

(b) None of the funds appropriated in this Act, and none of the funds in any trust fund to which funds are appropriated in this Act, shall be expended for health benefits coverage that includes coverage of abortion.

(c) The term “health benefits coverage” means the package of services covered by a managed care provider or organization pursuant to a contract or other arrangement.

SEC. 507 Limitations on Abortion Funding Prohibition

(a) The limitations established in the preceding section shall not apply to an abortion—

(1) if the pregnancy is the result of an act of rape or incest; or

(2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

(b) Nothing in the preceding section shall be construed as prohibiting the expenditure by a State, locality, entity, or private person of State, local, or private funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(c) Nothing in the preceding section shall be construed as restricting the ability of any managed care provider from offering abortion coverage or the ability of a State or locality to contract separately with such a provider for such coverage with State funds (other than a State’s or locality’s contribution of Medicaid matching funds).

(d)(1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(2) In this subsection, the term “health care entity” includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, and any other entity providing health care.
SEC. 508. Prohibits Use of Funds for Embryo Research

(a) None of the funds made available in this Act may be used for—

(1) the creation of a human embryo or embryos for research purposes; or

(2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term “human embryo or embryos” includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

SEC. 509. Prohibits Promotion of Legalization of Controlled Substances

(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act except for normal and recognized executive-congressional communications.

(b) The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

SEC. 515. (b) Prohibits Asking Candidates for Federal Scientific Advisory Committees Their Political Affiliations; Prohibits Distribution of Intentionally False Information

(b) None of the funds made available in this Act may be used to disseminate information that is deliberately false or misleading.

SEC. 520. Pornography.

(a) None of the funds made available in this Act may be used to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

(b) Nothing in subsection (a) shall limit the use of funds necessary for any Federal, State, tribal, or local law enforcement agency or any other entity carrying out criminal investigations, prosecution, or adjudication activities.

SEC. 521. Prohibits Funding ACORN or Its Affiliates or Subsidiaries. None of the funds made available under this or any other Act, or any prior Appropriations Act, may be provided to the Association of Community Organizations for Reform Now (ACORN), or any of its affiliates, subsidiaries, allied organizations, or successors.
SEC. 527. Prohibits Federal Funding for Needle Exchange Except in Limited Circumstances. Notwithstanding any other provision of this Act, no funds appropriated in this Act shall be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug: Provided, That such limitation does not apply to the use of funds for elements of a program other than making such purchases if the relevant State or local health department, in consultation with the Centers for Disease Control and Prevention, determines that the State or local jurisdiction, as applicable, is experiencing, or is at risk for, a significant increase in hepatitis infections or an HIV outbreak due to injection drug use, and such program is operating in accordance with State and local law.

Government-wide General Provisions

SEC. 718. Propaganda. No part of any appropriation contained in this or any other Act shall be used directly or indirectly, including by private contractor, for publicity or propaganda purposes within the United States not heretofore authorized by the Congress.

SEC. 732. Privacy Act. None of the funds made available in this Act may be used in contravention of section 552a of title 5, United States Code (popularly known as the Privacy Act), and regulations implementing that section.

SEC. 742. Confidentiality Agreements.

(a) None of the funds appropriated or otherwise made available by this or any other Act may be available for a contract, grant, or cooperative agreement with an entity that requires employees or contractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or contactors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

(b) The limitation in subsection (a) shall not contravene requirements applicable to Standard Form 312, Form 4414, or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

SEC. 743. Nondisclosure Agreements

(a) No funds appropriated in this or any other Act may be used to implement or enforce the agreements in Standard Forms 312 and 4414 of the Government or any other nondisclosure policy, form, or agreement if such policy, form, or agreement does not contain the following provisions: “These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this SEC. 743. (a) No funds appropriated in this or any other Act may be used to implement or enforce the agreements in Standard Forms
312 and 4414 of the Government or any other nondisclosure policy, form, or agreement if such policy, form, or agreement does not contain the following provisions: “These provisions are consistent with and do not supersede, conflict with, or otherwise alter the employee obligations, rights, or liabilities created by existing statute or Executive order relating to (1) classified information, (2) communications to Congress, (3) the reporting to an Inspector General of a violation of any law, rule, or regulation, or mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, or (4) any other whistleblower protection. The definitions, requirements, obligations, rights, sanctions, and liabilities created by controlling Executive orders and statutory provisions are incorporated into this agreement and are controlling.”: Provided, That notwithstanding the preceding provision of this section, a nondisclosure policy form or agreement that is to be executed by a person connected with the conduct of an intelligence or intelligence-related activity, other than an employee or officer of the United States Government, may contain provisions appropriate to the particular activity for which such document is to be used. Such form or agreement shall, at a minimum, require that the person will not disclose any classified information received in the course of such activity unless specifically authorized to do so by the United States Government. Such nondisclosure forms shall also make it clear that they do not bar disclosures to Congress, or to an authorized official of an executive agency or the Department of Justice, that are essential to reporting a substantial violation of law.

(b) A nondisclosure agreement may continue to be implemented and enforced notwithstanding subsection (a) if it complies with the requirements for such agreement that were in effect when the agreement was entered into.

(c) No funds appropriated in this or any other Act may be used to implement or enforce any agreement entered into during fiscal year 2014 which does not contain substantially similar language to that required in subsection (a).

SEC. 744. Unpaid Federal Tax Liability. None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

SEC. 745. Criminal Felony Limitation. None of the funds made available by this or any other Act may be used to enter into a contract, memorandum of understanding, or cooperative agreement with, make a grant to, or provide a loan or loan guarantee to, any corporation that was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.
Other Appropriations Provisions

42 U.S.C. 289d note No funds appropriated under this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used by the National Institutes of Health, or any other Federal agency, or recipient of Federal funds on any project that entails the capture or procurement of chimpanzees obtained from the wild. For purposes of this section, the term ‘recipient of Federal funds’ includes private citizens, corporations, or other research institutions located outside of the United States that are recipients of Federal funds.

Other Statutory Provisions

Trafficking in Persons
This award is subject to the requirements of Section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104)

a. Provisions applicable to a recipient that is a private entity.
1. You as the recipient, your employees, subrecipients under this award, and subrecipients' employees may not
   i. Engage in severe forms of trafficking in persons during the period of time that the award is in effect;
   ii. Procure a commercial sex act during the period of time that the award is in effect; or
   iii. Use forced labor in the performance of the award or subawards under the award.
2. We as the Federal awarding agency may unilaterally terminate this award, without penalty, if you or a subrecipient that is a private entity –
   i. Is determined to have violated a prohibition in paragraph a.1 of this award term; or
   ii. Has an employee who is determined by the agency official authorized to terminate the award to have violated a prohibition in paragraph a.1 of this award term through conduct that is either-
      A. Associated with performance under this award; or
      B. Imputed to you or the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 CFR part 376.

b. Provisions applicable to a recipient other than a private entity.
We as the Federal awarding agency may unilaterally terminate this award, without penalty, if a subrecipient that is a private entity-
1. Is determined to have violated an applicable prohibition in paragraph a.1 of this award term; or
2. Has an employee who is determined by the agency official authorized to terminate the award to have violated an applicable prohibition in paragraph a.1 of this award term through conduct that is either
   i. Associated with performance under this award; or
   ii. Imputed to the subrecipient using the standards and due process for imputing the conduct of an individual to an organization that are provided in 2 CFR part 180, "OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)," as implemented by our agency at 2 CFR part 376.

c. Provisions applicable to any recipient.
1. You must inform us immediately of any information you receive from any source alleging a violation of a prohibition in paragraph a.1 of this award term.

2. Our right to terminate unilaterally that is described in paragraph a.2 or b of this section:
   i. Implements section 106(g) of the Trafficking Victims Protection Act of 2000 (TVPA), as amended (22 U.S.C. 7104(g)), and
   ii. Is in addition to all other remedies for noncompliance that are available to us under this award.

3. You must include the requirements of paragraph a.1 of this award term in any subaward you make to a private entity.

**d. Definitions.** For purposes of this award term:

1. "Employee" means either:
   i. An individual employed by you or a subrecipient who is engaged in the performance of the project or program under this award; or
   ii. Another person engaged in the performance of the project or program under this award and not compensated by you including, but not limited to, a volunteer or individual whose services are contributed by a third party as an in-kind contribution toward cost sharing or matching requirements.

2. "Forced labor" means labor obtained by any of the following methods: the recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery.

3. "Private entity":
   i. Means any entity other than a State, local government, Indian tribe, or foreign public entity, as those terms are defined in 2 CFR 175.25.
   ii. Includes:
      A. A nonprofit organization, including any nonprofit institution of higher education, hospital, or tribal organization other than one included in the definition of Indian tribe at 2 CFR 175.25(b).
      B. A for-profit organization.


**Whistleblower Protections**

You are hereby given notice that the 48 CFR section 3.908, implementing section 828, entitled “Pilot Program for Enhancement of Contractor Employee Whistleblower protections,” of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2013 (Pub. L. 112-239, enacted January 2, 2013) applies to this award.

**Human Subjects Protections**

If any activities under this project will involve human subjects in any research activities, you must provide satisfactory assurance of compliance with the participant protection requirement of the HHS/OASH Office of Human Research Protection (OHRP) prior to implementation of those research components. This assurance should be submitted to the OHRP in accordance with the appropriate regulations.
Fraud, Abuse and Waste:
The HHS Inspector General accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in Department of Health and Human Services' programs. Your information will be reviewed promptly by a professional staff member. Due to the high volume of information that they receive, they are unable to reply to submissions. You may reach the OIG through various channels.

Internet: https://forms.oig.hhs.gov/hotlineoperations/index.aspx
Phone: 1-800-HHS-TIPS (1-800-447-8477)
Mail: US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
PO Box 23489
Washington, DC 20026
For additional information visit https://oig.hhs.gov/fraud/report-fraud/index.asp