II

116TH CONGRESS
2D SESSION

S. 5082

To provide Federal support for COVID–19 testing, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 21, 2020

Ms. WARREN introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide Federal support for COVID–19 testing, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Expanding COVID–19 Testing Capacity Act of 2020''.

(b) TABLE OF CONTENTS.—The table of contents for the Act is as follows:

SEC. 2. DEFINITIONS.

In this Act:

(1) ASSOCIATED MEDICAL SUPPLIES.—The term ''associated medical supplies'' means any product necessary for the development and administration of COVID–19 diagnostic tests, including chemical reagents, test swabs, and personal protective equipment (including surgical masks, surgical gowns, face shields, gloves, and N95 masks).

(2) COVID–19 DIAGNOSTIC TEST.—The term ''COVID–19 diagnostic test'' means a test—

(A) that is an in vitro diagnostic product (as defined in section 809.3 of title 21, Code of Federal Regulations, or any successor thereto) for the detection of SARS–CoV–2 or the diagnosis of COVID–19; and

(B) the administration of which—

(i) 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); or

(ii) the developer has received an 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.

(3) COVID–19 PANDEMIC.—The term ''COVID–19 pandemic'' means the period beginning on the date that the public health emergency with respect to COVID–19 took effect, and ending on the date that is 6 months after the date on which the public health emergency declaration with respect to COVID–19 terminates.

(4) INDIAN TRIBE.—Except as otherwise provided, the term ''Indian Tribe'' has the meaning given the term ''Indian tribe'' in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(5) PUBLIC HEALTH EMERGENCY WITH RESPECT TO COVID–19.—The term ''public health emergency with respect to COVID–19'' means the public health emergency declared by the Secretary under section 319 of the Public Health Service Act (21 U.S.C. 247d) on January 31, 2020, with respect to COVID–19.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(7) TRIBAL ORGANIZATION.—Except as otherwise provided, the term ''Tribal organization'' has

the meaning given the term ''tribal organization'' in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304).

(8) URBAN INDIAN ORGANIZATION.—The term ''urban Indian organization'' has the meaning given the term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

SEC. 3. FEDERAL MANUFACTURING OF COVID–19 DIAGNOSTIC TESTS.

(a) IN GENERAL.—As soon as practicable after the date of enactment of this Act, but no later than 15 days after such date of enactment, the Secretary shall begin the process of manufacturing, or contracting with entities for the manufacture of, COVID–19 diagnostic tests and associated medical supplies, with a particular focus on extraction-free highly sensitive molecular tests, pooled highly sensitive molecular tests, low-cost rapid antigen test, low-cost highly sensitive molecular tests, assays that can use a variety of reagents, and other products as determined by the Secretary. The Secretary shall continue such process until the end of the COVID–19 pandemic.

(b) SUBMISSION OF APPLICATIONS.—For each COVID–19 diagnostic test and associated drug or device that the Secretary intends to market, or contract with another entity for the marketing of, the Secretary shall—

(1) submit an application under subsection (b) or (j) of section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or subsection (a) or (j) of section 351 of the Public Health Service Act (42 U.S.C. 262), submit a notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), or submit a request for classification under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) (or enter into a contract with another entity to submit such an application, notification, or request);

(2) request an emergency use authorization of the product under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) (or enter into a contract with another entity to submit an application for such use); or

(3) obtain from the holder of an application approved under subsection (c) or (j) of section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act or subsection (a) or (k) of section 351 of the Public Health Service Act, or cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act, rights to manufacture such product.

(c) PROVISION OF PRODUCTS.—With respect to COVID–19 diagnostic tests and associated drugs and devices manufactured pursuant to subsection (a), the Secretary shall—

(1) provide such COVID–19 diagnostic tests and associated medical supplies at no cost to Federal, State, local, territorial, and Native health programs, and other domestic health care providers, including domestic commercial health care providers, as determined by the Secretary; and

(2) sell additional tests and associated drugs and devices, at-cost, to other commercial entities and international entities not described in paragraph (1).

(d) OBTAINING RIGHTS TO MANUFACTURE AND MARKET.—

(1) IN GENERAL.—When necessary to fulfill the Secretary's duties under this section, the Secretary shall acquire the rights to manufacture and market COVID–19 diagnostic tests and associated drugs and devices as authorized under this section.

(2) LICENSING AUTHORITY.—

(A) IN GENERAL.—Notwithstanding any other provision of law, the Secretary may issue licenses, as useful for fulfilling the duties under this Act, allowing the Department of Health

and Human Services to practice or have practiced (which may include licensure of retroactive practice) any invention in the United States or territories of the United States, including making, using, offering to sell or selling, importing, or exporting such invention, to reference or rely upon clinical trial data submitted to a regulatory authority or the grant of marketing approval, and to access and use otherwise confidential information, including know-how, related to the manufacture of COVID–19 diagnostic tests and associated medical supplies.

(B) NON-VOLUNTARY LICENSING.—For any license that involves a non-voluntary authorization to use patented inventions, regulatory test data, data, know-how or other intellectual property rights, the license shall provide for reasonable remuneration to rights holders such as a reasonable royalty on the sales of product, a 1-time payment, or some combination, provided that the combined royalty payments to all rights holders shall not exceed the percentage of sales that is the average percent of all royalty payments reported to the Internal Revenue Service by companies in the pharma-

ceutical and medicines sector, North American Industry Classification System code 325410, provided that when products are distributed for free, the royalty shall be based upon the cost of goods. When there are multiple rights holders, the allocation of the total royalty payments shall be determined by—

(i) agreement among the rights holders;

(ii) allocation by arbitration among the rights holders; or

(iii) if neither clause (i) nor (ii) applies, by the Secretary.

(3) TRANSPARENCY.—Subject to paragraph (4), the Secretary shall post any contract agreement under subsection (a) or license issued under paragraph (2)(A) on the public internet website of the Department of Health and Human Services, on the date on which such agreement or license takes effect.

(4) PROTECTED INFORMATION.—In carrying out this section, the Secretary shall enforce applicable law concerning the protection of confidential commercial information and trade secrets.

(e) PRICING DETERMINATIONS.—

(1) AT-COST PRICE.—In determining an at-cost price for COVID–19 diagnostic tests and associated medical supplies for purposes of subsection (c)(2), the Secretary shall consider—

(A) the cost to the Federal Government of manufacturing the applicable COVID–19 diagnostic test or associated drug or device; and

(B) the cost to acquire or manufacture under subparagraph (A) the applicable COVID–19 diagnostic test or associated drug or device.

(2) TRANSPARENCY.—All prices charged for COVID–19 diagnostic tests and associated medical supplies shall be made publicly available by the Secretary.

(f) AWARDING CONTRACTS.—

(1) PRIORITY.—In awarding contracts under this section, the Secretary shall prioritize entities manufacturing COVID–19 diagnostic tests or associated medical supplies using components originating from, and manufactured in, the United States.

(2) CONTRACT REQUIREMENTS.—All contracts issued under this section shall include a requirement that the contract recipients reasonably price products produced under the contract.

(g) REPORT TO THE PRESIDENT AND CONGRESS.—The Secretary shall prepare and submit to the President, the Committee on Health, Education, Labor, and Pensions of the Senate, and the Committee on Energy and Commerce of the House of Representatives, a monthly report during the COVID–19 pandemic, and a final report 3 months after such pandemic has concluded, that includes—

(1) an assessment of the major supply chain challenges facing health care facilities, medical providers, the Federal Government, State, local, territorial, and Tribal governments, and the private sector in COVID–19 diagnostic tests and associated medical supplies; and

(2) a description of the authorization or approval status and available supply of all COVID–19 diagnostic tests and associated medical supplies for which manufacturing has been authorized under this section, including products for which the Secretary has submitted an application for approval, a notification for clearance, or a request for classification to the Food and Drug Administration but has not yet received approval, clearance, or classification, and products for which the Secretary has received approval, clearance, or classification, from the Food

and Drug Administration but are not being manufactured.

(h) PROCEEDS FROM SALES.—There are authorized to be appropriated to the Secretary for each fiscal year, for purposes of carrying out this section, an amount equal to the proceeds from the sale of COVID–19 diagnostic tests and associated medical supplies described in subsection (c)(2) in the previous fiscal year.

SEC. 4. COVID–19 TESTING FOR COVERED FEDERAL EMPLOYEES.

(a) DEFINITIONS.—In this section:

(1) AGENCY.—The term ''agency''—

(A) means—

(i) each agency, office, or other establishment in the executive, legislative, or judicial branch of the Federal Government, including—

(I) an Executive agency, as that term is defined in section 105 of title 5, United States Code;

(II) a military department, as that term is defined in section 102 of title 5, United States Code;

(III) the Federal Aviation Administration;

(IV) the Transportation Security Administration;

(V) the Department of Veterans Affairs;

(VI) the Government Accountability Office;

(VII) the Library of Congress;

(VIII) the Postal Service;

(IX) the House of Representatives;

(X) the Senate; and

(XI) the Architect of the Capitol;

(ii) the District of Columbia courts and the District of Columbia Public Defender Service; or

(iii) an—

(I) Indian Tribe or Tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.);

(II) Indian Tribe or Tribal organization that receives a grant under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2501 et seq.); or

(III) Indian Tribe or Tribal organization (as defined in section 5212 of the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2511)) that receives a grant under that Act (25 U.S.C. 2501 et seq.); and

(B) does not include a nonappropriated fund instrumentality under the jurisdiction of the Armed Forces.

(2) COVERED DUTY.—The term ''covered duty'' means all work performed by a Federal employee, except duties that a Federal employee performs while teleworking from a residence.

(3) FEDERAL EMPLOYEE.—The term ''Federal employee'' means—

(A) an individual who engages in covered duties on behalf of an agency at any time during the COVID–19 pandemic, or an individual classified as an independent contractor by the agency who engages in covered duties during such period;

(B) includes—

(i) any person performing work for an agency who engages in covered duties during the COVID–19 pandemic, regardless of

whether such person is classified as an independent contractor by the agency; and

(ii) any paid or unpaid intern, fellow, trainee, or other person performing work for an agency who engages in covered duties during the COVID–19 pandemic; and

(C) does not include any employee of a Federal contractor.

(4) TIMELY MANNER.—The term ''timely manner'', with respect to the administration of a COVID–19 diagnostic test, means within 24 hours of the administration of such test.

(b) FEDERAL EMPLOYEE COVID–19 TESTING.—

(1) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, each agency shall begin to—

(A) conduct or contract with entities to conduct COVID–19 diagnostic tests for Federal employees employed by the agency at no cost to the employee, regardless of whether such employees exhibit symptoms of COVID–19, provided at locations accessible to the Federal employees;

(B) provide each Federal employee employed by the agency with the results of the di-

agnostic tests, regardless of the results, including an interpretation of what the test means in the employee's preferred language, in a timely manner;

(C) submit the results of such tests to relevant Federal, State, local, territorial, and Tribal public health officials; and

(D) publish the aggregate results of such diagnostic tests in accordance with section 8.

(2) TIME PERIOD.—Each agency shall continue the activities described in subparagraphs (A), (B), and (C) of paragraph (1) throughout the duration of the COVID–19 pandemic.

(3) MINIMUM WAGE AND OVERTIME.—Notwithstanding any other provision of law, for any individual employed by a contractor or subcontractor, and who performs work assisted in whole or in part by funding under this section, with respect to such employment, such individual shall—

(A) be paid a wage of not less than $15 per hour; and

(B) if such individual is paid at a rate that is the full-time equivalent of less than $51,000 per year, receive overtime pay of one-and-one-half times the individual's regular rate of pay

for all hours worked in excess of 40 hours per workweek.

(c) FREQUENCY AND LOCATION OF COVID–19 DIAGNOSTIC TESTING.—In administering COVID–19 tests pursuant to subsection (b), each agency shall provide COVID–19 diagnostic tests at frequencies and locations recommended by the State, local, territorial or Tribal public health officials with jurisdiction over the geographic areas in which the applicable Federal employees work, or, if a national testing strategy is developed by Federal officials, in compliance with the national testing strategy.

(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to each Federal agency such sums as may be necessary to procure and administer the COVID–19 diagnostic tests required under this section.

SEC. 5. FEDERAL DISTRIBUTION OF COVID–19 TESTS TO QUALIFIED ENTITIES.

(a) DEFINITIONS.—In this section:

(1) COVID–19 TESTING.—The term ''COVID–19 testing'' has the meaning given such term in interim final rules promulgated by the Secretary within 15 days of the date of enactment of this Act.

(2) ESSENTIAL WORK.—The term ''essential work'' means any work that—

(A) is performed during the period of the COVID–19 pandemic;

(B) cannot be performed while teleworking from a residence; and

(C)(i) involves—

(I) regular in-person interactions with patients, the public, or coworkers of the individual performing the work; or

(II) regular physical handling of items that were handled by, or are to be handled by patients, the public, or coworkers of the individual performing the work; and

(ii) is in the area of—

(I) first responder work, in the public sector or private sector, including services in response to emergencies that have the potential to cause death or serious bodily injury, such as police, fire, emergency medical, protective, child maltreatment, domestic violence, and correctional services (including activities carried out by employees in fire protection activities, as defined in section 3(y) of the Fair Labor Standards Act of 1938 (29 U.S.C. 203(y)) and activities of law enforcement officers, as defined

in section 1204(6) of the Omnibus Crime Control and Safe Streets Act of 1968 (34 U.S.C. 10284(6)));

(II) health care work physically provided in inpatient settings (including hospitals and other inpatient post-acute care settings such as nursing homes, inpatient rehabilitation facilities, and other related settings) and other work physically performed in such inpatient settings that supports or is in furtherance of such health care work physically provided in inpatient settings;

(III) health care work physically provided in outpatient settings (including at physician offices, community health centers, Tribal clinics, rural health clinics and other clinics, hospital outpatient departments, freestanding emergency departments, health centers, ambulatory surgical centers, dialysis centers, dental offices, and other related settings), and other work physically performed in such outpatient settings that supports or is in furtherance

of such health care work physically provided in outpatient settings;

(IV) pharmacy work, physically performed in pharmacies, drug stores, or other retail facilities specializing in medical goods and supplies;

(V) any work physically performed in a facility that performs medical testing and diagnostic services, including laboratory processing, medical testing services, imaging services, or related activities;

(VI) home- and community-based health care work, including home health care, residential care, assistance with activities of daily living, and any services provided by direct care workers (as defined in section 799B of the Public Health Service Act (42 U.S.C. 295p)), personal care aides, community health aides and community health aides participating in the Community Health Representative Program or the Community Health Aide Program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.), job coaches, or supported employment pro-

viders, and any other provision of care to individuals in their homes by direct service providers, personal care attendants, and home health aides;

(VII) biomedical research;

(VIII) behavioral health work requiring physical interaction with individuals, including mental health services and substance use disorder prevention, treatment, and recovery services;

(IX) nursing care and residential work physically provided in a facility;

(X) family care, including child care services, in-home child care services such as nanny services, and care services provided by family members to other family members;

(XI) social services work, including social work, case management, social and human services, child welfare, family services, shelter and services for people who have experienced intimate partner violence or sexual assault, services for individuals who are homeless, child services, commu-

nity food and housing services, and other emergency social services;

(XII) public health work conducted at a State, local, territorial, or Tribal government public health agency, including epidemiological activities, surveillance, contact tracing, data analysis, statistical research, health education, and other disease detection, prevention, and response methods;

(XIII) work conducted at a hospital, clinic, triage center, or other permanent or temporary health facility operated by the Indian Health Service, an Indian Tribe, Tribal organization, or urban Indian organization;

(XIV) grocery work physically performed at grocery stores, supermarkets, convenience stores, corner stores, drug stores, retail facilities specializing in medical goods and supplies, bodegas, or another location where individuals purchase non-prepared food items;

(XV) restaurant work, including carry-out, drive-thru, or food delivery

work, requiring physical interaction with individuals or food products;

(XVI) food production work involving the physical interaction with food products, including all agricultural work, farming, harvesting, fishing, forestry, ranching, processing, canning, slaughtering, packaging, baking, butchering, and other food production work, such as any service or activity described in section 3(f) of the Fair Labor Standards Act of 1938 (29 U.S.C. 203(f)) or section 3121(g) of the Internal Revenue Code of 1986, and the handling, planting, drying, packing, packaging, processing, freezing, or grading prior to delivery for storage of any agricultural or horticultural commodity in its unmanufactured state;

(XVII) transportation work, including—

(aa) any services in public transportation, as defined in section 5302(14) of title 49, United States Code;

(bb) any private transportation of people, such as transportation provided by air, rail, bus, taxicab, personal car or truck, non-motorized vehicle, or otherwise, including all services performed by individuals working in or on such vehicles, vehicle depots, or transit facilities;

(cc) any services in passenger rail transportation, including commuter rail, intercity passenger rail, or Amtrak, including services performed by employees of contractors of such entities;

(dd) any services in the transportation of persons, property, or mail by an aircraft of an air carrier conducting operations under part 121 of title 14, Code of Federal Regulations (or successor regulations), or a foreign air carrier within, to, or from the United States, either on board an aircraft or on the ground at an airport, including services performed by employees of contractors of air carriers,

or foreign air carriers, as described in section 4111(3) of the CARES Act (15 U.S.C. 9071(3));

(ee) any services as an aircraft mechanic or technician who performs maintenance, repair, or overhaul work on an aircraft of an air carrier conducting operations under such part 121 or foreign air carrier within the United States;

(ff) services as maritime workers who qualify as seamen under section 10101(3) of title 46, United States Code, and other maritime employees including—

(AA) longshoremen, harbor workers and shipbuilders covered under section 2(3) of the Longshore and Harbor Workers' Compensation Act (33 U.S.C. 902(3)) involved in the transportation of merchandise or passengers by water; and

(BB) shipbuilders and ship repairers who are working for an

employer performing shipbuilding or ship repair work under contract or subcontract to the Departments of Defense, Energy or Homeland Security for military or other national security purposes;

(gg) services as maritime transportation workers supporting or enabling transportation functions, including such services as—

(AA) barge workers, tug operators, and port and facility security personnel;

(BB) marine dispatchers; and

(CC) workers who repair and maintain marine vessels (including the equipment and infrastructure that enables operations that encompass movement of cargo and passengers); and

(hh) work physically performed in a warehouse or other facility in warehousing (including all services

performed by individuals picking, sorting, packing, and shipping in warehouses), storage, distribution, or call center support facilities, and other essential operational support functions that are necessary to accept, store, and process goods, and that facilitate the goods' transportation and delivery;

(XVIII) cleaning work and building maintenance work physically performed on the grounds of a facility, including all custodial or janitorial services, security services, and repair and maintenance services;

(XIX) work in the collection, removal, transport, storage, or disposal of residential, industrial, or commercial solid waste and recycling, including services provided by individuals who drive waste or recycling trucks, who pick up waste or recycling from residential or commercial locations, or who work at waste or recycling centers or landfills;

(XX) work in the gathering, processing, disseminating, and delivery of news and information that serves the public in-

terest to the public through mass media, including television, radio, and newspapers;

(XXI) any work performed by an employee of a State, locality, or Tribal government, that is determined to be essential work by the highest authority of such State, locality, or Tribal government;

(XXII) educational work, school nutrition work, and other work required to operate a school facility, including early childhood and after-school enrichment programs, preschool programs, elementary and secondary education, and higher education;

(XXIII) laundry work, including work in laundromats, laundry service companies, and dry cleaners;

(XXIV) elections work physically performed at polling places or otherwise amongst the public, including public-sector elections personnel and private-sector elections personnel;

(XXV) hazardous materials management, response, and cleanup work associated with any other essential work covered

under this paragraph, including health care waste (including medical, pharmaceuticals, and medical material production), and testing operations (including laboratories processing test kits);

(XXVI) disinfection work for all facilities and modes of transportation involved in other essential work covered under this paragraph;

(XXVII) work in critical clinical research, development, and testing necessary for COVID–19 response that involves physical interaction with hazardous materials, such as samples of COVID–19;

(XXVIII) work in mortuary, funeral, cremation, burial, cemetery, and related services;

(XXIX) work requiring physical interactions with patients in physical therapy, occupational therapy, speech-language pathology, and respiratory therapy and other therapy services;

(XXX) dental care work requiring physical interaction with patients;

(XXXI) work performed by employees of the United States Postal Service;

(XXXII) work at hotel and commercial lodging facilities that are used for COVID–19 mitigation and containment measures; and

(XXXIII) work installing or repairing a telecommunications line or equipment.

(3) ESSENTIAL WORKER.—The term ''essential worker'' means an individual whose work and duties include essential work, including individuals that are employees of employers and individuals performing any services or labor for remuneration, regardless of whether such individual is classified as an independent contractor by the employer.

(4) QUALIFIED ENTITY.—The term ''qualified entity'' means—

(A) a congregate care setting, including any skilled nursing facilities, assisted living facilities, prisons and jails, residential behavioral health care and psychiatric facilities, and facilities providing services for aging adults and people with disabilities;

(B) an education center, including any childcare facilities, elementary and secondary

schools that have resumed (or plan to resume within 30 days of receipt of items under subsection (b)) any form of in-person instruction, and colleges and universities that have resumed (or plan to resume within 30 days of receipt of items under subsection (b)) any form of in-person instruction or on-campus housing;

(C) a community center, such as State and local government buildings, religious centers, and nonprofit service organizations;

(D) a prison, jail, or youth detention facility;

(E) a hospital, community health center, Tribal or Indian Health Service clinic or hospital, or other medical facility;

(F) a small business;

(G) a business that employs essential workers;

(H) a homeless shelter or entity supporting individuals living in housing funded with support from the Department of Housing and Urban Development, including housing provided under the supportive housing for the elderly program under section 202 of the Housing Act of 1959 (12 U.S.C. 1701q); or

(I) another entity, as determined by the Secretary, that could serve as a COVID–19 diagnostic testing site.

(5) TIMELY MANNER.—The term ''timely manner'', with respect to the administration of a COVID–19 diagnostic test, means within 24 hours of the administration of such test.

(b) DISTRIBUTION OF COVID–19 DIAGNOSTIC TESTS.—

(1) IN GENERAL.—Within 40 days of the date of enactment of this Act, the Secretary shall—

(A) begin distributing COVID–19 diagnostic tests and associated medical supplies, including tests and medical supplies manufactured under section 3, to qualified entities via State, local, territorial, and Tribal governments for the purpose of—

(i) providing COVID–19 diagnostic testing to essential workers and individuals served by qualified entities, at no cost to the essential workers and individuals, regardless of whether such workers and individuals exhibit symptoms of COVID–19, at locations accessible to the essential workers and individuals in the course of their work;

(ii) providing essential workers and individuals served by qualified entities with the results of the diagnostic tests, regardless of the results, including an interpretation of what the test means in the employee's preferred language, in a timely manner;

(iii) submitting the results of such tests to relevant Federal, State, local, territorial, and Tribal public health officials; and

(iv) publishing the aggregate results of such diagnostic tests in accordance with section 8; and

(B) hire and deploy employees, or contract with outside entities to hire and deploy employees, as necessary to assist in the distribution, provision, administration of, and data collection regarding COVID–19 diagnostic tests as described in subparagraph (A).

(2) EMPLOYEES.—In hiring employees, or contracting with outside entities to hire employees, to carry out this subsection, the Secretary shall prioritize, or require contractors to prioritize, hiring

individuals from within the communities served by the applicable qualified entity.

(3) MINIMUM WAGE AND OVERTIME.—Notwithstanding any other provision of law, for any individual employed by a contractor or subcontractor, and who performs work assisted in whole or in part by funding under this section, with respect to such employment, such individual shall—

(A) be paid a wage of not less than $15 per hour; and

(B) if such individual is paid at a rate that is the full-time equivalent of less than $51,000 per year, receive overtime pay of one-and-one-half times the individual's regular rate of pay for all hours worked in excess of 40 hours per workweek.

(c) COORDINATION WITH STATE, LOCAL, TERRITORIAL, AND TRIBAL GOVERNMENTS.—Within 30 days of the date of enactment of this Act, a representative of each State, local, territorial, and Tribal government shall submit to the Secretary a list of qualified entities in their jurisdiction and a description of employee, resource, and other infrastructure needs necessary for the distribution of COVID–19 diagnostic tests and associated drugs and devices under subsection (b).

(d) FREQUENCY AND LOCATION OF COVID–19 DIAGNOSTIC TESTING.—In distributing COVID–19 tests under (b), the Secretary shall provide COVID–19 diagnostic tests at frequencies and locations recommended by the State, local, territorial, or Tribal public health officials with jurisdiction over the geographic areas in which qualified entities are located, or, if a national testing strategy is developed by Federal officials, in compliance with the national testing strategy.

(e) PUBLIC REPORTING.—Beginning 30 days after the date of enactment of this Act and for the duration of the COVID–19 pandemic, the Secretary shall publish weekly, in a machine readable format, the total number of tests distributed to, and the total number of tests administered in, each State, county, territory, and Tribe under subsection (b).

(f) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as may be necessary to carry out this section.

SEC. 6. SUPPLEMENTAL GRANTS FOR COVID–19 TESTING.

(a) IN GENERAL.—No later than 30 days after the date of enactment of this Act, the Secretary, acting through the Director of the Centers for Disease Control and Prevention shall—

(1) issue competitive grants to State, local, and territorial governments for the purpose of increasing access to COVID–19 diagnostic testing; and

(2) issue noncompetitive and formula-based awards to Indian Tribes and Tribal organizations.

(b) PRIORITY AREAS AND POPULATIONS.—In issuing grants under subsection (a), the Secretary shall—

(1) prioritize areas and populations that have been disproportionately affected by COVID–19, and areas where operationalizing testing programs is not possible with existing resources; and

(2) consider the capacity that States, localities, territories, and Tribes already have at the time of application to conduct widespread COVID–19 diagnostic testing.

(c) USE OF FUNDS.—Grants awarded under subsection (a) may be used to—

(1) establish new COVID–19 diagnostic testing sites at community centers, such as State, local, territorial, and Tribal government buildings, churches, health centers, clinics, and public parks, subject to Federal quality control standards for laboratory testing;

(2) hire State, local, territorial, and Tribal government employees, or contract with outside entities,

to assist in the development, distribution, and provision of COVID–19 diagnostic tests within the State, locality, territory, or Tribe;

(3) purchase COVID–19 diagnostic tests and the medical supplies necessary to conduct such tests;

(4) increase the number of COVID–19 diagnostic tests provided at congregate settings, such as—

(A) skilled nursing facilities;

(B) assisted living facilities;

(C) childcare facilities;

(D) elementary and secondary schools that have resumed, or plan to resume within 30 days, in-person instruction;

(E) colleges and universities that have resumed, or plan to resume within 30 days, in-person instruction or on-campus housing;

(F) prisons, jails, and youth detention facilities;

(G) residential behavioral health care and psychiatric facilities;

(H) institutions providing services for aging adults and people with intellectual and developmental disabilities, rehabilitation facilities, and group homes; and

(I) homeless shelters;

(5) educate the public about the availability of COVID–19 diagnostic tests in their communities and what to do if a positive result is received;

(6) issue subgrants, cooperative agreements, or contracts to labs, hospitals, and other test providers to reduce test processing time; submit the results to State, local, territorial, and Tribal public health officials; and prevent delays in the distribution of testing results, such as through transferring research lab capacity to COVID–19 testing capacity and building new labs to reduce test processing turnaround time;

(7) enable the State, locality, territory, or Tribe to detect and identify trends in COVID–19 and develop guidance for communities on how to develop testing programs and expand test capacity;

(8) reduce disparities in access to COVID–19 diagnostic testing among the communities hardest hit by COVID–19; and

(9) additional uses, as determined by the Secretary, in accordance with subsection (e).

(d) REQUIREMENT.—Any COVID–19 diagnostic test conducted with the support of a grant awarded under this section shall be provided to patients free of charge and

without regard for immigration status. The results shall be submitted to relevant State, local, territorial, and Tribal public health officials.

(e) MINIMUM WAGE AND OVERTIME.—Notwithstanding any other provision of law, for any individual employed by a contractor or subcontractor, and who performs work assisted in whole or in part by funding under this section, with respect to such employment, such individual shall—

(1) be paid a wage of not less than $15 per hour; and

(2) if such individual is paid at a rate that is the full-time equivalent of less than $51,000 per year, receive overtime pay of one-and-one-half times the individual's regular rate of pay for all hours worked in excess of 40 hours per workweek.

(f) ADDITIONAL USES OF FUNDS.—In determining appropriate uses of funds under subsection (c)(9), the Secretary shall consider the incidence of COVID–19 in States, localities, territories, and Tribes, the availability and uptake of vaccines for COVID–19 in States, localities, territories, and Tribes, and advancements in COVID–19 diagnostic test technologies.

(g) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated $25,000,000,000 for fiscal year 2021 for purposes of awarding grants under this section.

(2) TRIBAL SET-ASIDE.—Not less than 10 percent of the total amount appropriated under paragraph (1) for a fiscal year shall be reserved for non-competitive awards to—

(A) Indian Tribes or Tribal organizations carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5301 et seq.);

(B) Indian Tribes or Tribal organizations receiving a grant under the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2501 et seq.); and

(C) Indian Tribes or tribal organizations (as defined in section 5212 of the Tribally Controlled Schools Act of 1988 (25 U.S.C. 2511)) receiving grants under that Act (25 U.S.C. 2501 et seq.).

(3) LOCAL GOVERNMENT SET ASIDE.—Not less than 30 percent of the total amount appropriated under paragraph (1) for a fiscal year shall be reserved for grants awarded directly to local governments.

SEC. 7. REPORTS AND GUIDANCE ON COVID–19 DIAGNOSTIC TESTING.

(a) UPDATED GUIDANCE ON COVID–19 RAPID DIAGNOSTIC TESTS.—

(1) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue updated guidance on the development of rapid COVID–19 diagnostic tests, the provision of such tests, including in nonclinical environments, and the appropriate collection and electronic reporting of results (including geographic and demographic data, including with respect to race and ethnicity) and data regarding such tests to Federal, State, local, and Tribal public health officials.

(2) RAPID COVID–19 DIAGNOSTIC TEST.—For purposes of paragraph (1), the term ''rapid COVID–19 diagnostic test'' means a COVID–19 diagnostic test that can be performed by a user, with or without the need of a medical professional or medical supervisor, and that can produce results within 1 hour of application.

(b) UPDATED SURVEILLANCE TESTING GUIDANCE.—

(1) IN GENERAL.—Not later than 30 days after the date of enactment of this Act, the Secretary, act-

ing through the Commissioner of Food and Drugs and in consultation with the Director of the Centers for Disease Control and Prevention, shall issue guidance on COVID–19 surveillance testing best practices. Such guidance shall address how COVID–19 surveillance testing can be used to keep qualified entities, as defined in section 5(a), open to the public, and how tests with differing accuracy standards, including rapid point of care antigen tests and pooled molecular tests, can each be used in COVID–19 surveillance testing at qualified entities among children and adult.

(2) COVID–19 SURVEILLANCE TESTING.—For purposes of paragraph (1), the term ''COVID-19 surveillance testing'' means the ongoing, systematic collection, analysis, and interpretation of COVID–19 diagnostic test results for the purpose of monitoring for a community- or population-level infection and disease, or to characterize the incidence and prevalence of disease.

(c) REPORT ON NATIONAL DAILY TESTING BENCHMARK.—Not later than 30 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Director of the Centers for Disease Control and Preven-

tion, shall issue recommendations on the total number of COVID–19 diagnostic tests that should be conducted in the United States per day to control the spread of COVID–19, with a focus on the number of tests necessary to protect essential workers, as defined in section 5(a), from COVID–19 infection.

(d) COMPARISON OF COVID–19 DIAGNOSTIC TEST PERFORMANCE.—Not later than 30 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall issue a report comparing the performance of COVID–19 diagnostic tests on the market, including a comparison of the differing sensitivity and accuracy of such tests in asymptomatic and symptomatic populations and children and adults.

(e) REVIEW OF COVID–19 DIAGNOSTIC TEST APPROVAL PATHWAYS.—Not later than 30 days after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall review the process for approving COVID–19 diagnostic tests for market, with a particular focus on extraction-free highly sensitive molecular tests, pooled highly sensitive molecular tests, low-cost rapid antigen test, low-cost highly sensitive molecular tests, assays that can use a variety of reagents, and other products as determined by the Sec-

retary, and take steps as necessary to expedite such process, as appropriate.

SEC. 8. DEMOGRAPHIC AND GEOGRAPHIC DATA COLLECTION.

(a) COVID–19 DATA COLLECTION.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator of the Centers for Medicare & Medicaid Services and the Director of the Indian Health Service, shall make publicly available on the website of the Centers for Disease Control and Prevention data collected relating to COVID–19 testing from entities receiving Federal funding under this Act, including data disaggregated by race, ethnicity, sex (including sexual orientation and gender identity), age, primary language, socioeconomic status, disability status, pregnancy status, occupation, county, and zip code.

(b) APPLICATION OF STANDARDS.—To the extent practicable, data collection under this section shall follow standards developed by the Office of Minority Health of the Department of Health and Human Services and the Centers for Disease Control and Prevention, and shall be collected, analyzed, and reported in accordance with the standards promulgated under section 3101 of the Public Health Service Act (42 U.S.C. 300kk).

(c) TIMELINE.—The data made available under this section shall be updated on a weekly basis throughout the COVID–19 pandemic.

(d) PRIVACY.—In publishing data under this section, the Secretary shall take all necessary steps to protect the privacy of individuals whose information is included in such data, including—

(1) complying with privacy protections provided under the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and State law; and

(2) protections from all inappropriate internal use by an entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from inappropriate uses.

(e) DATA USE.—Neither the Secretary, nor any other officer or employee of the Federal Government, or local government liaison, may use the information furnished under this legislation for any purpose other than the statistical and public health purposes for which such information is supplied, or make any publication whereby the data furnished by any particular establishment or individual under this Act can be identified, or permit anyone other

than the sworn officers and employees of the Department of Health and Human Services to examine the individual reports.

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