2025-1363

United States Court of Appeals for the Federal Circuit

CHRIS J. KROENUNG,

Petitioner

v.

DEPARTMENT OF DEFENSE,

Respondent

Petition for Review from the Merit Systems Protection Board
in CH-0752-23-0234-I-1

SUPPLEMENTAL APPENDIX

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Safer Federal Workforce Task Force

COVID-19 Workplace Safety: Agency Model Safety Principles

Last Updated September 13, 2021 (Previously Updated July 29, 2021)

Recent Updates

- Federal Executive Branch employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. Agencies must work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021.
- With the government-wide adoption and implementation of these vaccination requirements, agencies are no longer required to establish a screening testing program for employees or onsite contractor employees who are not fully vaccinated, although they may do so.
- The President has announced that Federal contractor employees will be required to be vaccinated. Prior to being contractually required to be vaccinated, onsite contractor employees who are not fully vaccinated and are not part of an agency testing program must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building.

Purpose

The purpose of this document is to provide model safety principles for executive departments and agencies (hereafter, "agency" and collectively, "agencies") for their COVID-19 workplace safety plans. In Executive Order No. 13991, President Biden established the Safer Federal Workforce Task Force to oversee the development and implementation of agency COVID-19 workplace safety plans across the Federal Government. In his Executive Order on *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees* and his Executive Order on *Ensuring Adequate COVID Safety Protocols for Federal Contractors*, President Biden directed the Task Force to issue guidance on implementation of the requirements in those Orders.

Agencies should incorporate these model safety principles into their existing COVID-19 workplace safety plans.

Agencies with onsite contractor employees should address how the protocols below are applied to those individuals to promote Federal workplace safety in the context of COVID-19.

Overview of Model Principles

The Federal Government is committed to addressing essential work requirements consistent with best public health practices. The Administration's paramount concern is the health and safety of all Federal employees, onsite contractor employees, and individuals interacting with the Federal workforce.

The principles presented here are aligned with the latest guidance from the Centers for Disease Control and Prevention (CDC) for employers and for fully vaccinated people and the Occupational Safety and Health Administration (OSHA) on protecting workers, based on evolving understanding of the pandemic. These principles will be reassessed over time, as conditions warrant and as CDC guidelines are updated.

Where a locality has imposed additional pandemic-related requirements more protective than those set forth in these model safety principles, those requirements should be followed in Federal buildings and on Federal land in that locality.

Goal

The health and safety of the Federal workforce is the Administration's highest priority.

Health and Safety

Vaccination

To ensure the safety of the Federal workforce, Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. Agencies must work expeditiously so that their employees are fully vaccinated as quickly as possible and by no later than November 22, 2021.

When a Federal employee is required to be vaccinated, the time the employee spends obtaining any COVID-19 vaccination (including travel time) is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. Employees may not be credited with administrative leave for time spent getting a vaccination. If, due to unforeseen circumstances, the employee is unable to obtain the vaccine during basic tour of duty hours the normal overtime hours of work rules apply.

Employees will receive paid time off to address any side effects. Employees will also receive paid time off to accompany a family member being vaccinated. For this purpose, a "family member" is an individual who meets the definition of that term in OPM's leave regulations (see 5 CFR 630.201).

Some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status. Given the different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated, agencies need to ask about the vaccination status of visitors to Federal buildings and onsite contractor employees who are not yet contractually required to be vaccinated. Individuals must attest to the truthfulness of the response they provide. When an individual discloses that they are not fully vaccinated or declines to provide information on their vaccination status, agencies should treat that individual as not fully vaccinated for purposes of implementing safety measures, including with respect to mask wearing and physical distancing.

Onsite contractor employees who are not yet contractually required to be vaccinated and who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building—as noted below, if a contractor employee is regularly tested pursuant to an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Visitors to Federal buildings who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building. See the section below on Meetings, Events, and Conferences

for how visitor requirements apply to in-person participants in meetings, events, and conferences hosted by agencies.

These requirements related to the provision of information about vaccination and provision of proof of a recent negative COVID-19 test do not apply to members of the public entering a Federal building or Federal land to obtain a public service or benefit. If they are not fully vaccinated, these visitors must comply with all relevant CDC guidance, including wearing a mask and physically distancing from other people.

Levels of Community Transmission

For purposes of this guidance, when determining levels of community transmission in a given area, agencies should reference the CDC COVID-19 Data Tracker County View. Agencies can use discretion in determining the counties relevant to the determination of the level of community transmission in a given area for a given Federal facility. For example, agencies may consider the county in which an agency facility is located as well as the transmission levels of surrounding local counties from which employees commute to the facility.

Telework and Remote Work

Agencies should utilize telework and remote work consistent with the principles set forth in OMB Memorandum M-21-25 and agency plans for reentry and post-reentry.

COVID-19 Coordination Team

Each agency should maintain its COVID-19 Coordination Team, as detailed in OMB Memorandum M-21-15. This team should, at a minimum, include a representative from: each component agency (if applicable); the appropriate human resources office(s); occupational safety and health experts; executive leadership; legal counsel; and a public health expert. If such a public health expert does not exist at the agency, the Safer Federal Workforce Task Force will designate someone. The team should meet regularly to review compliance with agency COVID-19 workplace safety plans and protocols, consider potential revisions to agency COVID-19 workplace safety plans and protocols pursuant to guidance from the Safer Federal Workforce Task Force and current CDC guidelines, and evaluate any other operational needs related to COVID-19 workplace safety. The team should coordinate all decisions with Facility Security Committees, as appropriate. For privately owned facilities leased by the Federal Government, the team must coordinate with the General Services Administration (GSA), where appropriate, and the lessor's designated representative.

Face Masks and Physical Distancing

Federal employees must be fully vaccinated, except in limited circumstances where an employee is legally entitled to a reasonable accommodation. In addition, some contractor employees may not yet be subject to a contractual requirement to be vaccinated, and some visitors may not be fully vaccinated or decline to provide information on their vaccination status.

Individuals who are not fully vaccinated must wear a mask regardless of community transmission level. In areas of high or substantial transmission, fully vaccinated people must wear a mask in public indoor settings, except for limited exceptions discussed in this section.

In areas of low or moderate transmission, in most settings, fully vaccinated people generally do not need to wear a mask or physically distance in Federal buildings or on Federal land, except where required by Federal, State, local, Tribal, or territorial laws, rules, or regulations. Fully vaccinated individuals might choose to wear a mask regardless of the level of transmission for a variety of reasons. Nothing in CDC guidance precludes an employee from wearing a mask, if the employee so chooses. CDC's guidance for mask wearing and physical distancing in specific settings, including healthcare, transportation, correctional and detention facilities, and schools, should be followed, as applicable.

Individuals who are not fully vaccinated or who decline to provide their vaccination status—or who are in an area of substantial or high transmission—must wear a mask that covers their nose and mouth, and that is in accordance with current CDC guidance. CDC recommends the following: disposable masks, masks that fit properly (snugly around the nose and chin with no large gaps around the sides of the face), masks made with breathable fabric (such as cotton), masks made with tightly woven fabric (i.e., fabrics that do not let light pass through when held up to a light source), masks with two or three layers, and masks with inner filter pockets. Agencies should not allow novelty or non-protective masks, masks with ventilation valves, or face shields as a substitute for masks.

In addition to properly wearing a mask, individuals who are not fully vaccinated or who decline to provide information about their vaccination status must maintain distance. To the extent practicable, individuals who are not fully vaccinated or who decline to provide information about their vaccination status should maintain a distance of at least six feet from others at all times, consistent with CDC guidelines, including in offices, conference rooms, and all other communal and work spaces.

For individuals who are required to wear a mask:

- Appropriate masks should be worn consistently and correctly (over mouth and nose).
- Appropriate masks should be worn in any common areas or shared workspaces (including open floorplan office space, cubicle embankments, and conference rooms).
- In general, people do not need to wear masks when outdoors. However, consistent with CDC guidance, those who are not fully vaccinated should wear a mask in crowded outdoor settings or during outdoor activities that involve sustained close contact with other people who are not fully vaccinated.
- Agencies may provide for exceptions consistent with CDC guidelines, for example, when an individual is alone in an office with floor to ceiling walls and a closed door, or for a limited time when eating or drinking and maintaining distancing in accordance with CDC guidelines.

Masked individuals may be asked to lower their masks briefly for identification purposes in compliance with safety and security requirements.

Masks do not provide the same level of protection as respirators and should not replace personal protective equipment required or recommended at the workplace.

Testing

Agencies may establish a program to test Federal employees who are not fully vaccinated for COVID-19. Agencies may also test contractor employees working onsite who are not fully vaccinated as part of a

testing program—if contractor employees are tested as part of an agency testing program, they do not need to provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building unless required to by the agency testing program.

Agencies must have a process in place for employee diagnostic testing after a workplace exposure.

Contact Tracing

The agency's COVID-19 Coordination Team will collaborate with and support the contact tracing programs of local health departments to help identify, track, and manage contacts of COVID-19 cases.

The team will engage in coordination with facilities staff to implement infection control and workplace safety efforts once informed of a known or suspected case of COVID-19 (due either to specific symptoms or a positive test).

The team should ensure that the agency makes disclosures to local public health officials, as required or necessary, to provide for the health and safety of Federal employees, contractor employees, and the general public, in accordance with local public health mandates. If COVID-19 cases occur within a specific building or work setting, it will be the responsibility of that agency's COVID-19 Coordination Team (or a field office or agency component designee) to determine—in consultation with local public health officials—appropriate next steps. Agencies should be transparent in communicating related information to the workforce, as relevant and appropriate; disclosures must be consistent with Federal, State, and local privacy and confidentiality laws and regulations.

Travel

Federal employees should adhere strictly to CDC guidelines before, during, and after travel.

For Federal employees who are fully vaccinated, there are no Government-wide restrictions on travel (although agency travel policies still apply).

For the limited number of Federal employees who are not fully vaccinated, agencies should generally observe the following guidance, unless it is contrary to a reasonable accommodation to which an employee is legally entitled. Official domestic travel should be limited to only necessary mission-critical trips. International travel should also be avoided, if at all possible, unless it is mission critical (e.g., military deployments, COVID-19 response deployments or activities, diplomats traveling, high-level international negotiations that cannot occur remotely). Heads of agencies should issue specific guidance to account for the particulars of their agency's mission.

Meetings, Events, and Conferences

Should an agency intend to host an in-person meeting, conference, or event that will be attended by more than 50 participants—regardless of whether participants include members of the public—the agency must first seek the approval of its agency head, in consultation with the agency's COVID-19 Coordination Team.

In-person attendees at any meetings, conferences, and events hosted by an agency, regardless of size, must be asked to provide information about vaccination status. In requesting this information, agencies should comply with any applicable Federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act. In-person attendees who are not fully vaccinated or decline to provide

information about their vaccination status must provide proof of a negative COVID-19 test completed no later than the previous 3 days and comply with masking and physical distancing requirements for individuals who are not fully vaccinated consistent with the requirements for visitors in the Face Masks and Physical Distancing section above. In-person attendees in areas of high or substantial transmission must wear a mask in public indoor settings regardless of vaccination status.

Symptom Monitoring

If Federal employees, onsite contractors, or visitors have symptoms consistent with COVID-19, they should not enter a Federal workplace.

Federal employees and contractor employees working on site should regularly complete virtual or in-person health checks (ask about symptoms, close contact with someone with SARS-CoV-2 infection, and SARS-CoV-2 testing and diagnosis status). The agency will use this information to assess the individual's risk level and to determine whether the individual should be allowed entry to the workplace. Visitors may be asked to complete symptom screening before entering a Federal facility. In developing these tools, agencies may adapt the one developed by CDC.

Any individual, regardless of vaccination status, who develops any symptoms consistent with COVID-19 during the workday must immediately isolate, wear a mask (if the individual is not already doing so and one is available), notify their supervisor, and promptly leave the workplace. Agencies should have processes in place to provide advice and support to supervisors on any related reporting or human resources requirements.

Quarantine, Isolation, and Steps for Fully Vaccinated Individuals Following Exposure to Someone with Suspected or Confirmed COVID-19

Any individual with a suspected or confirmed case of COVID-19 will be advised to isolate, pursuant to CDC guidelines, and in compliance with State, local, and Tribal laws and regulations. Personnel who are not fully vaccinated and who have had a close contact with someone who has tested positive for COVID-19 should follow CDC and State, local, and Tribal guidance for quarantine.

Individuals who have been fully vaccinated and have had close contact with someone with suspected or confirmed COVID-19 should get tested 3-5 days after exposure, even if they do not have symptoms. They should also wear a mask indoors in public for 14 days following exposure or until their test result is negative. If their test result is positive, they should isolate for 10 days.

Confidentiality and Privacy

All medical information collected from individuals, including vaccination information, test results, and any other information obtained as a result of testing and symptom monitoring, will be treated in accordance with applicable laws and policies on confidentiality and privacy, and will be accessible only to those with a need to know. Agencies should consult their Senior Agency Officials for Privacy on matters related to the handling of personally identifiable information and identify a point of contact for all questions relating to personal medical information.

Workplace Operations

Occupancy

Agencies may establish occupancy limits for specific workplaces as a means of facilitating physical distancing. Note that by reducing the number of people in a space, occupancy limits also increase the heating, ventilation, and air conditioning delivery of outdoor air per person.

Environmental Cleaning

Agencies should ensure regular cleaning of common use, high-touch, and high-density spaces, such as lobbies, restrooms, elevators, and stairwells. Office space that is in regular use is to be cleaned regularly, and in accordance with CDC guidelines. Wipes and other Environmental Protection Agency-approved disinfectants will be made available for use by individuals to wipe down workstations and related personal property. Physical barriers, such as plexiglass shields, may be installed, where appropriate.

In the event of a suspected or confirmed case of COVID-19 in the workplace, agencies should ensure enhanced environmental cleaning of the spaces that the individual occupied or accessed in accordance with CDC and, where applicable, GSA guidance, which provides as follows:

- If fewer than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, clean and disinfect the space.
- If more than 24 hours have passed since the person who is sick or diagnosed with COVID-19 has been in the space, cleaning is enough. You may choose to also disinfect depending on certain conditions or everyday practices required by your facility.
- If more than 3 days have passed since the person who is sick or diagnosed with COVID-19 has been in the space, no additional cleaning (beyond regular cleaning practices) is needed.

If enhanced cleaning is required, wait as long as possible (at least several hours) before cleaning and disinfecting. Extended wait periods allow increased opportunity for viral deactivation to occur naturally, while also allowing time for aerosols to settle, prior to surface disinfection.

The agency's COVID-19 Coordination Team will determine the appropriate scope of workplace closures needed—in some cases, it may be a suite or individual offices or part of a floor, in other cases, it may include an entire building.

Hygiene

Hand sanitizer stations are to be available at the building entrance and throughout workspaces. Hand sanitizers should contain at least 60% alcohol and be manufactured in accordance with the requirements of the U.S. Food and Drug Administration (FDA). Ingredients should be listed on a "Drug Facts" label. Agencies should ensure the hand sanitizer is not on the FDA's do not use list.

Ventilation and Air Filtration

Modifications to ventilation systems should be considered in accordance with CDC guidance, especially as building population density increases. To the maximum extent feasible, indoor ventilation will be optimized to increase the proportion of outdoor air and improve filtration. Deployment of portable high-efficiency particulate air (HEPA) cleaners should be considered for higher-risk spaces (e.g., health clinics).

Collective Bargaining Obligations

Consistent with President Biden's policy to support collective bargaining, agencies are reminded to satisfy applicable collective bargaining obligations under 5 U.S.C. Chapter 71 when implementing workplace safety plans, including on a post-implementation basis where necessary. Agencies are also strongly encouraged to communicate regularly with employee representatives on workplace safety matters.

Presidential Documents

Executive Order 14043 of September 9, 2021

Requiring Coronavirus Disease 2019 Vaccination for Federal Employees

By the authority vested in me as President by the Constitution and the laws of the United States of America, including sections 3301, 3302, and 7301 of title 5, United States Code, it is hereby ordered as follows:

Section 1. *Policy.* It is the policy of my Administration to halt the spread of coronavirus disease 2019 (COVID–19), including the B.1.617.2 (Delta) variant, by relying on the best available data and science-based public health measures. The Delta variant, currently the predominant variant of the virus in the United States, is highly contagious and has led to a rapid rise in cases and hospitalizations. The nationwide public health emergency, first declared by the Secretary of Health and Human Services on January 31, 2020, remains in effect, as does the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) declared pursuant to the National Emergencies Act in Proclamation 9994 of March 13, 2020 (Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak). The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services has determined that the best way to slow the spread of COVID–19 and to prevent infection by the Delta variant or other variants is to be vaccinated.

COVID–19 vaccines are widely available in the United States. They protect people from getting infected and severely ill, and they significantly reduce the likelihood of hospitalization and death. As of the date of this order, one of the COVID–19 vaccines, the Pfizer-BioNTech COVID–19 Vaccine, also known as Comirnaty, has received approval from the Food and Drug Administration (FDA), and two others, the Moderna COVID–19 Vaccine and the Janssen COVID–19 Vaccine, have been authorized by the FDA for emergency use. The FDA has determined that all three vaccines meet its rigorous standards for safety, effectiveness, and manufacturing quality.

The health and safety of the Federal workforce, and the health and safety of members of the public with whom they interact, are foundational to the efficiency of the civil service. I have determined that ensuring the health and safety of the Federal workforce and the efficiency of the civil service requires immediate action to protect the Federal workforce and individuals interacting with the Federal workforce. It is essential that Federal employees take all available steps to protect themselves and avoid spreading COVID–19 to their co-workers and members of the public. The CDC has found that the best way to do so is to be vaccinated.

The Safer Federal Workforce Task Force (Task Force), established by Executive Order 13991 of January 20, 2021 (Protecting the Federal Workforce and Requiring Mask-Wearing), has issued important guidance to protect the Federal workforce and individuals interacting with the Federal workforce. Agencies have also taken important actions, including in some cases requiring COVID–19 vaccination for members of their workforce.

Accordingly, building on these actions, and in light of the public health guidance regarding the most effective and necessary defenses against COVID–19, I have determined that to promote the health and safety of the Federal workforce and the efficiency of the civil service, it is necessary to require COVID–19 vaccination for all Federal employees, subject to such exceptions as required by law.

Sec. 2. *Mandatory Coronavirus Disease 2019 Vaccination for Federal Employees.* Each agency shall implement, to the extent consistent with applicable law, a program to require COVID–19 vaccination for all of its Federal employees, with exceptions only as required by law. The Task Force shall issue guidance within 7 days of the date of this order on agency implementation of this requirement for all agencies covered by this order.

Sec. 3. *Definitions.* For the purposes of this order:

(a) The term ''agency'' means an Executive agency as defined in 5 U.S.C. 105 (excluding the Government Accountability Office).

(b) The term ''employee'' means an employee as defined in 5 U.S.C. 2105 (including an employee paid from nonappropriated funds as referenced in 5 U.S.C. 2105(c)).

Sec. 4. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

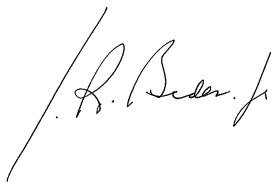
(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) If any provision of this order, or the application of any provision to any person or circumstance, is held to be invalid, the remainder of this order and the application of any of its other provisions to any other persons or circumstances shall not be affected thereby.



THE WHITE HOUSE,
September 9, 2021.

[FR Doc. 2021–19927
Filed 9–13–21; 8:45 am]
Billing code 3295–F1–P

October 1, 2021

Memorandum for Heads of Executive Departments and Agencies

From: Kiran A. Ahuja
Director

Subject: Guidance on Enforcing Coronavirus Disease 2019 Vaccination Requirement for Federal Employees – Executive Order 14043

Note: The guidance within the memorandum below has been rescinded by Executive Order 14099 "Moving Beyond COVID-19 Vaccination Requirements for Federal Workers."

On September 9, 2021, President Biden signed Executive Order (EO) 14043, titled, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees." As stated in Section 1 of the EO, the President has determined that in order to promote the health and safety of the workforce and the efficiency of the civil service, it is necessary for all agencies to require COVID–19 vaccination for Federal employees covered by EO 14043, subject only to such exceptions as required by law.

As directed in the EO, the Safer Federal Workforce Task Force, established by EO 13991 (January 20, 2021) ("Task Force"), has issued guidance to assist agencies with implementing the vaccination requirement. That guidance specifies that agencies should require all of their employees, with exceptions only as required by law, to be fully vaccinated by November 22, 2021.

People are considered fully vaccinated two weeks after their second shot in a two-dose series, or two weeks after a single-shot series. In order to have covered Federal employees vaccinated by November 22, 2021, agencies should inform employees of the following scheduling considerations, based on the type of vaccine they obtain:

- For Pfizer-BioNTech COVID-19 vaccine, individuals should get their second shot 3 weeks (or 21 days) after the first. This means that in order for Federal employees to meet a November 22 deadline, they should receive their first vaccination no later than October 18, and their second dose no later than November 8.

- For Moderna COVID-19 vaccine, individuals should get their second shot 4 weeks (or 28 days) after their first. This means that in order for Federal employees to meet a November 22 deadline, they should receive their first vaccination dose no later than October 11, and their second dose no later than November 8.

- Because the Johnson & Johnson/Janssen vaccine only has one shot, Federal employees must get that dose by November 8, in order to meet a November 22, 2021 deadline to be fully vaccinated.

Of course, it is advisable not to leave vaccinations to the last possible date, as other events often interfere with even well-laid plans.

Employees who refuse to be vaccinated or provide proof of vaccination are subject to disciplinary measures, up to and including removal or termination from Federal service. The only exception is for individuals who receive a legally required exception pursuant to established agency processes.

Given this timeline, agencies may initiate the enforcement process as soon as November 9, 2021, for employees who have not completed their vaccination dose(s) by November 8. The attached provides additional guidance for Federal agencies and employees on the recommended approach agencies should take regarding enforcement of the Coronavirus Disease 2019 vaccination requirement. Agencies should consult with agency human resources offices and legal counsel to determine application of agency disciplinary policies and collective bargaining agreement requirements on disciplinary matters.

Additional Information

Agency headquarters-level human resources offices may contact OPM at employeeaccountability@opm.gov with additional questions. Agency field offices should contact their appropriate headquarters-level agency human resources offices. Guidance from the Task Force is available at: https://www.saferfederalworkforce.gov/overview/

cc: Chief Human Capital Officers (CHCOs)
Deputy CHCOs
Human Resources Directors

Attachment – Enforcement Guidance (see 508-conformant PDF below)

Guidance on Enforcement of Coronavirus Disease 2019 Vaccination Requirement for Federal Employees – Executive Order 14043

Note: The guidance below has been rescinded by Executive Order 14099 "Moving Beyond COVID-19 Vaccination Requirements for Federal Workers."

1) Why is OPM issuing this guidance?

On September 9, 2021, the President signed Executive Order (EO) 14043, titled, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees." As reflected in Section 1 of the EO, the President has determined that in order to promote the health and safety of the workforce and the efficiency of the civil service, it is necessary to require COVID–19 vaccination for Federal employees, subject to such exceptions as are required by law. The U.S. Office of Personnel Management (OPM) is issuing this guidance to assist agencies in implementing this requirement for Federal employees subject to EO 14043 requirements.

2) What agencies and employees are covered by the EO 14043 vaccination requirement?

Section 3 of EO 14043 defines which agencies and employees are covered by the vaccination requirement. Agencies should consult with their legal offices to determine agency and employee coverage under EO 14043.

3) What is the deadline for federal employees to be fully vaccinated?

Safer Federal Workforce Task Force guidance specifies that agencies should require all of their employees, with exceptions only as required by law, to be fully vaccinated by November 22, 2021. That means employees must complete required vaccination dose(s) by November 8, as they will not become "fully vaccinated" until 2 weeks after their final dose (the second of 2 doses for Pfizer and Moderna, and the first dose for Johnson and Johnson). The only exception is for individuals who receive a legally required exception approved under established agency processes.

4) What should an agency do to inform employees about the requirement to be fully vaccinated?

OPM recommends an agency should not delay in providing employees with information regarding the benefits of vaccination and ways to obtain the vaccine. Such information is available on the Centers for Disease Control and Prevention website. Agencies should consider a variety of methods to educate employees, such as providing information in employee town halls, posting of information on agency intranet sites, email communications directly to employees, and providing information in regular staff meetings.

As part of the education process, agencies should inform employees of the requirement to be fully vaccinated in compliance with EO 14043 and that failure to comply will result in disciplinary action up to and including removal or termination. In addition, it is advisable for agencies to send to their workforce periodic reminders of this requirement and the consequences for non-compliance. To be fully vaccinated by November 22, 2021, employees must receive their final vaccination dose by November 8, 2021.

5) When can an agency initiate the enforcement process for failure to comply with the requirement to be fully vaccinated?

Agencies may initiate the enforcement process as soon as November 9, 2021, for employees who have not received their required vaccination dose by November 8, 2021, unless the employee has received an exception or the agency is considering an exception request from the employee.

6) Is there a recommended approach to enforcement?

Agencies must comply with all statutory, regulatory, and collective bargaining agreement requirements (where applicable). If the employee has not provided proof of vaccination by November 8, 2021, and has not received an exception and the agency is not considering an exception request from the employee, OPM recommends agencies initiate the enforcement process with counseling and education. Agencies should use the counseling period to remind the employee again of the vaccination requirement, emphasize that failure to comply will lead to discipline up to and including removal or termination, address any questions, and inform the employee that they will have a short period of time (e.g., 5 days) to submit documentation establishing either the initiation or completion of vaccination, as applicable, or request an exception.

If, after the recommended counseling and education period ends, the individual continues to refuse to comply, the agency should pursue disciplinary measures, up to and including removal or termination from Federal service. In pursuing any disciplinary action, the agency must provide the required procedural rights to an employee and follow normal processes, including any agency policies or collective bargaining agreement requirements concerning disciplinary matters. Employees generally should not be placed on administrative leave while the agency pursues disciplinary action for refusal to be vaccinated but will be required to follow safety protocols for employees who are not fully vaccinated when reporting to agency worksites. Agencies may wish to consult with counsel as to any other mechanisms that might be available to address the situation.

Agencies are reminded that generally the objective of discipline is to correct deficiencies in employee conduct. Discipline can deter misconduct and correct situations interfering with the efficiency of civil service. While the law and OPM adverse action regulations do not require progressive discipline, this is the preferred approach in the instance of non-compliance with the requirement to be vaccinated. With this in mind, agencies are strongly encouraged to consider whether lesser disciplinary penalties are adequate, as an initial matter, to encourage an employee to be vaccinated, such as a short suspension of 14 days or less under procedures established under 5 CFR 752.203[1] (or procedures for similar matters which arise under other personnel systems). If a short suspension proves inadequate in encouraging an employee to

[1] 5 CFR 752.203 does not apply to actions against Administrative Law Judges (ALJs) or employees in the Senior Executive Service (SES). Please refer to Subchapter III, Chapter 75 of Title 5, United States Code, for adverse action procedures for ALJs and Subpart F of 5 CFR Part 752 for adverse action procedures for SES. Please note that suspensions of 14 days or less are not available for SES.

become vaccinated, agencies should then consider a greater disciplinary penalty, such as removal or termination from the Federal service, under procedures established under 5 CFR 752.404,[2] 5 CFR part 315, subpart H (for probationers), or procedures for similar matters which arise under other personnel systems.

Agencies should strive for similar penalties for similarly situated employees, where appropriate, within the same work unit. To facilitate this for larger organizations where actions may be necessary for multiple employees, an agency should consider designating one management official to be a proposing official and designating another management official to be a deciding official for all actions in the work unit.

7) What should an agency do if, after initiating the disciplinary process by proposing to take an action, the agency is informed by the employee that the employee has received a vaccination?

If, after November 8, 2021, and prior to the issuance of a decision during the disciplinary process, such as suspension or removal, an employee provides an agency with appropriate documentation that the employee is now fully vaccinated, the disciplinary process should end. If an employee provides an agency with appropriate documentation after November 8, 2021, that the employee has received the first dose in a 2-dose series vaccine, an agency may hold any disciplinary action in abeyance pending receipt of appropriate documentation that the employee has received the second dose within the designated 3 or 4-week interval depending on the vaccine received by the employee, even if this means the employee will not be fully vaccinated until after November 22, 2021. In these instances, the employee will be required to follow all appropriate safety protocols if reporting to an agency worksite. The employee should be provided a deadline for receiving the final dose of the vaccine and providing appropriate documentation.

8) What should an agency do if an employee is serving a suspension and provides documentation to the agency that they are now fully vaccinated or have received the first dose in a 2-dose series vaccine?

If, during the time period a suspension is being served by an employee, the employee provides an agency with appropriate documentation that the employee is now fully vaccinated, the agency may end the suspension. If, during the time period a suspension is being served by an employee, the employee provides an agency with appropriate documentation that the employee has received the first dose in a 2-dose series vaccine, an agency may hold the balance of the suspension in abeyance. The employee should be provided a deadline of no more than 5 weeks from the date of receiving the first dose for receiving the final dose of the vaccine and providing appropriate documentation. Additionally, the agency should advise employees that the suspension will continue and they

[2] 5 CFR 752.404 does not apply to actions against Administrative Law Judges (ALJs) or employees in the Senior Executive Service (SES). Please refer to Subchapter III, Chapter 75 of Title 5, United States Code, for adverse action procedures for ALJs and Subpart F of 5 CFR Part 752 for adverse action procedures for SES. Please note that suspensions of 14 days or less are not available for SES.

may be subject to removal or termination if they fail to receive the final dose of the vaccine or fail to provide appropriate documentation by the new deadline.

9) Why can an employee be disciplined for refusing to get vaccinated or refusing to provide documentation of vaccination?

If an employee receives a direct order to receive a vaccine as required under EO 14043 and refuses, this is an act of misconduct. Any adverse actions for misconduct taken under 5 CFR Part 752 are taken for such cause as will promote the efficiency of the service. When taking an action under 5 CFR Part 752, agencies should consider relevant aggravating and mitigating factors when determining the penalty. See *Douglas v. Veterans Administration*, 5 MSPR 280 (1981). Agencies should consult with their human resources and legal offices in making these determinations.

There is precedent for taking an adverse action against a Federal employee for disobeying an order to be vaccinated. In *Mazares v. Department of Navy*, 302 F.3d 1382 (2002), for instance, two civilian Navy employees challenged their removals for refusing to receive an anthrax vaccination. The court found there was a clear and unjustified refusal to obey a lawful order of a superior.

10) What should an agency do if the employee claims they are legally entitled to be excepted from the vaccination requirement?

An agency should not initiate discipline if the employee claims a legally required exception as the reason proffered for not being vaccinated or providing proof of vaccination. If an employee claims a legally required exception, an agency should follow its ordinary process to review and consider what, if any, accommodation it must offer. All agency personnel designated to receive requests for accommodations should know how to handle requests consistent with any Federal employment nondiscrimination laws that may apply.

An employee whose request for an accommodation is denied should receive their first (or, if a one-dose series, only) dose within two weeks of the final determination to deny the accommodation. If receiving a two-dose series, the employee should receive the second dose within 6 weeks of receiving the first dose.

If the employee received a first dose of a two-dose series prior to seeking an accommodation, and their request for an accommodation is denied, they should receive their second dose within two weeks of the final determination to deny the accommodation or within a week of the earliest day by which they can receive their second dose, whichever is later.

If the employee does not comply with the requirement to become fully vaccinated, and has not been granted an exception and does not have a request under consideration, the agency may pursue disciplinary action, up to and including removal or termination from Federal service. If the accommodation request is denied, employees should be reminded again of the benefits of getting a COVID-19 vaccine and reminded that failure to comply with the vaccination requirement will result in disciplinary action, up to and including removal or termination from Federal service.

11) How should agencies enforce the vaccination requirement of Executive Order 14043 for employees on extended leave of absence (e.g., due to a serious health condition of themselves or a family member, or due to utilizing paid parental leave)?

Agencies should require employees on extended leave of absence (e.g., utilizing annual leave, sick leave, donated annual leave, military leave, leave without pay, paid parental leave, or unpaid leave under Family and Medical Leave) to submit documentation establishing that they are fully vaccinated (or request a legally required exception) prior to the employee returning to duty. Agencies should not require such employees to be vaccinated by a November 22, 2021 deadline, as long as they are on extended leave of absence and will not return to work until a later date.

12) How should agencies enforce the vaccination requirement of Executive Order 14043 for employees on extended leave of absence due to receiving workers compensation as a result of sustaining an on-the-job injury or illness?

Agencies should require employees on extended leave of absence due to receiving workers compensation to submit documentation establishing that they are fully vaccinated (or request a legally required exception) prior to the employee returning to duty. Agencies should not require such employees to be vaccinated by a November 22, 2021 deadline, as long as they are on extended leave of absence due to receiving workers compensation and will not return to duty until a later date.

13) How should agencies enforce the vaccination requirement of Executive Order 14043 for seasonal employees who are not currently working for an agency under their seasonal appointment?

Agencies should require seasonal employees to submit documentation establishing that they are fully vaccinated (or request a legally required exception) prior to the employee returning to duty. Agencies should not require such employees to be vaccinated by a November 22, 2021 deadline, as long as they will not return to duty until a later date.

14) How should agencies enforce the vaccination requirement of Executive Order 14043 for student volunteers, interns, or other employees who are on an extended break in service (e.g., interns who worked for an agency this past summer, returned to school, and are expected to return to work for the agency after the school year ends)?

Agencies should require student volunteers, interns, and other employees who are on an extended break to submit documentation establishing that they are fully vaccinated (or request a legally required exception) prior to returning to Federal service. Agencies should not require such persons to be vaccinated by a November 22, 2021 deadline, as long as they will not be reemployed until a later date.

15) How should agencies enforce the vaccination requirement of Executive Order 14043 for employees who are on detail?

Agencies should require employees who are on detail to another executive branch agency covered by EO 14043 to comply with the vaccination requirement of EO 14043. In accordance with the guidance issued by the Safer Federal Workforce Task Force, agencies should require detailed employees to be fully vaccinated by November 22, 2021. Detailed employees should follow the procedures of their home agency for submitting documentation to demonstrate their compliance with the vaccination requirement.

Agencies should require employees who are detailed to positions outside of an executive branch agency covered by EO 14043 to submit documentation establishing that they are fully vaccinated (or request a legally required exception) prior to the employee returning to duty at their home agency.

16) How should agencies enforce the vaccine requirement of Executive Order 14043 for employees who are running down their leave in advance of departing federal service and do not intend to return to duty before leaving?

If an employee has provided notice that they are leaving their position in the Executive Branch and are on leave until the date they depart, the agency should not enforce the vaccine requirement of EO 14043.

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

MAR 17 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Force Health Protection Guidance (Supplement 18) – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces During the Coronavirus Disease 2019 Pandemic

References: (a) Department of Defense Instruction (DoDI) 6200.03, "Public Health Emergency Management (PHEM) Within the DoD," March 28, 2019
(b) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 15) Revision 1 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services," March 15, 2021
(c) Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 8) – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces During the Public Health Emergency of the Coronavirus Disease 2019 Pandemic," April 13, 2020 (hereby rescinded)
(d) DoDI 5400.11, "DoD Privacy and Civil Liberties Programs," January 29, 2019, as amended
(e) DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019
(f) DoDI 6055.07, "Mishap Notification, Investigation, Reporting, and Record Keeping," June 6, 2011, as amended
(g) DoDI 6055.12, "Hearing Conservation Program (HCP)," August 14, 2019, as amended
(h) Secretary of Defense Memorandum, "Use of Masks and Other Public Health Measures," February 4, 2021

This memorandum further supplements requirements regarding the coronavirus disease 2019 (COVID-19) pandemic in accordance with reference (a) and rescinds reference (c). The Centers for Disease Control and Prevention (CDC) is continuously updating science-based guidance to slow the spread of the COVID-19 pandemic, including guidance to prevent transmission of the disease in workplaces. All DoD Components will continually implement appropriate procedures to protect all personnel from disease transmission in DoD workplaces.

Restrict Workplace Access

Subject to mission requirements, commanders and supervisors will take the following steps: minimize close contact between individuals in the workplace to maintain at least 6 feet of separation from others where possible; and assign telework if possible to decrease normal space occupancy.

DoD Components will further restrict access to DoD-controlled workplaces by individuals whom the CDC recommends[1] not go to work or otherwise enter work spaces, to the fullest extent practical consistent with mission needs. Current CDC Guidance for Businesses and Employers may be found at: **https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html#anchor_1609683582250**. Additional requirements follow:

- Personnel who have symptoms of COVID-19 (e.g., fever, cough, or shortness of breath) should notify their supervisor and stay home (**https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html**). Personnel who develop any symptoms consistent with COVID-19 during the workday must immediately isolate, notify their supervisor, and promptly leave the workplace.

- Sick personnel should follow CDC-recommended steps, which may be found at **https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html**. Personnel who had COVID-19 should not return to work until the criteria to discontinue home isolation, which may be found at **https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html**, are met, and in consultation with healthcare providers and State and local health departments.

- Asymptomatic, non-immunized personnel with potential exposure to COVID-19 based upon close contact with a person who has a laboratory confirmed, clinically diagnosed, or presumptive case should notify their supervisor. They should follow CDC-recommended precautions at: **https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html#precautions**. "Close contact" means a person has spent more than a total of 15 minutes in a 24-hour period within 6 feet of a COVID-19 infected individual. Close contact includes the time period of contact starting from 2 days before illness onset (or, for asymptomatic persons, 2 days prior to test specimen collection). If individuals become symptomatic during the duty period, they should be sent home immediately.

    - As a general rule, such asymptomatic, non-immunized personnel with potential exposure to COVID-19 should not return to the workplace until they have a confirmed negative COVID-19 test as described in reference (b) or following the appropriate self-quarantine period (e.g., 14 days starting on the last day traveling or starting on the date on which close contact occurred). Quarantine may be done

[1] Because the COVID-19 pandemic requires evolving assessments and recommendations, DoD Components must regularly consult CDC and DoD guidance for updated recommendations.

in the same residence with separate rooms and a separate bathroom, if the COVID-19 positive individual is a family member or other co-inhabitant. Personnel performing duties outside the United States also will follow applicable geographic Combatant Commander guidance as to whether and how to address host nation policies. Supervisors of DoD civilian employees should also consult with human resources to determine the appropriate status for the employee.

- In cases of mission-essential activities that must be conducted on site, as determined by those with the authority to provide exceptions as indicated below, non-immunized asymptomatic personnel who otherwise would be self-quarantining may be granted an exception to continue to work on site provided they remain asymptomatic, do not have a positive test for COVID-19, and comply with the following key practices for 14 days after the last exposure: obtain a COVID-19 test following CDC's testing guidelines at: **https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html**; conduct daily pre-screening with temperature checks; self-monitor with supervision by a commander or supervisor; wear a mask, practice hand and cough hygiene; do not share headsets or other objects used near the face; continue to social distance as much as possible; and clean and disinfect their workspaces daily. This exception may be granted by the first general/flag officer or member of the Senior Executive Service (SES), or equivalent, in the chain of command/chain of supervision and, for those locations that do not have general/flag officers or SES leaders, by O-6 installation commanders. If the individual becomes symptomatic during the duty period, he/she will be sent home immediately. Additional CDC guidance on implementing safety practices for essential services may be found at: **https://www.cdc.gov/coronavirus/2019-ncov/community/workplaces-businesses/essential-services.html**.

- Personnel who have tested positive for COVID-19 within the past 3 months and who have recovered are not required to remain out of the workplace even if they have been in close contact with someone who is suspected or confirmed to be infected with COVID-19 in accordance with CDC guidance at: **https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html**.

- Fully vaccinated personnel as defined by CDC at: **https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html** are not required to remain out of the workplace if they have been in close contact with a person who has a laboratory confirmed, clinically diagnosed or presumptive case of COVID-19.

In States and localities that require members of the general public to stay at home, DoD Service members and civilian employees may report to work as directed to do so by a commander or supervisor.

Collecting Information Necessary to Protect the Workplace

Due to the public health emergency, the collection by DoD Components of COVID-19 information from individuals whose place of duty is in the DoD workplace, to the extent such collection is necessary to implement the guidance above on workplace access, is authorized. DoD Components are authorized to use DD Form 3112, "Personnel Accountability and Assessment Notification for Coronavirus Disease 2019 (COVID-19) Exposure," to collect this information. This form is located at: **https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd3112.pdf**.

- This collection of information is consistent with requirements of the health information privacy regulations under reference (e).

- This collection of information also does not conflict with recent COVID-19 guidance from the Equal Employment Opportunity Commission under the Rehabilitation Act of 1973, 29 U.S.C. § 791, et seq., as amended.

- All personally identifiable information (PII) on individuals must be appropriately safeguarded in accordance with reference (d). In implementing this memorandum, DoD Components may collect, use, maintain, and/or disseminate only the minimum amount of PII necessary to prevent the spread of COVID-19 and to protect personnel in DoD workplaces.

- If an individual reports to their supervisor that they believe they contracted COVID-19 due to exposure in the workplace, the supervisor will report this as a suspected occupational illness to supporting safety and occupational health staff as required by reference (f). The determination of work-relatedness and required recording and reporting will follow part 1904 of title 29, Code of Federal Regulations, as interpreted at: **https://www.osha.gov/coronavirus/faqs#reporting**.

Implementing Procedures

In implementing this memorandum, DoD Components will comply with other applicable procedural requirements.

- Information will be collected and maintained consistent with the Privacy Act, as applicable. For reference, please note that the Privacy Act system of records notice for personnel accountability and assessment may be found at: **https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/OSDJS/DPR-39-DoD.pdf**.

- Implementation of this guidance will also comply with applicable labor obligations to the extent such obligations do not hinder the DoD Component's ability to carry out its missions during this emergency.

- DoD Components will, through applicable contracting officers, instruct contractors to take the steps necessary to ensure that their employees whose place of duty is in a DoD workplace adhere to the workplace access restrictions required by this memorandum.

Annual Audiometric Testing

The annual survey requirements specified in paragraph 3.8.c of reference (g) may be suspended by DoD Components during the COVID-19 pandemic so long as there is a good faith effort to complete required services and compliance is not otherwise possible. These requirements should resume upon the conclusion of the pandemic, upon removal of travel restrictions or return to HPCON "0," whichever comes later.

Frequently Asked Questions (FAQs)

Attached is a listing of frequently asked questions with responses that provide guidance that will be implemented for a consistent approach to addressing many occupational safety and health issues associated with COVID-19 response activities.

DoD force health protection guidance regarding COVID-19 may be found at **https://www.defense.gov/Explore/Spotlight/Coronavirus**. Commanders, supervisors, and individuals should frequently check the CDC COVID-19 website for additional updates at: **https://www.cdc.gov/coronavirus/2019-ncov/community/workplaces-businesses/index.html**. In addition, the Occupational Safety and Health Administration has published worker protection guidance at: **https://www.osha.gov/**. My point of contact for this guidance is Mr. Steve Jones, who may be reached at steven.p.jones10.civ@mail.mil or (703) 681-7335.

Virginia S. Penrod

Virginia S. Penrod
Acting

Attachment:
As stated

UNDER SECRETARY OF DEFENSE
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PERSONNEL AND
READINESS

JUL - 2 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Force Health Protection Guidance (Supplement 15) Revision 2 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services

References: (a) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 15) Revision 1 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services," March 15, 2021 (hereby rescinded)
(b) Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 11) – Department of Defense Guidance for Coronavirus Disease 2019 Surveillance and Screening with Testing," June 11, 2020
(c) Department of Defense Instruction (DoDI) 6440.02, "Clinical Laboratory Improvement Program (CLIP)," May 29, 2014
(d) Deputy Secretary of Defense Memorandum, "Coronavirus Task Force Diagnostics and Testing Line of Effort Transition of Functions," May 3, 2021
(e) DoDI 6040.45, "DoD Health Record Life Cycle Management," November 16, 2015
(f) DoDI 6055.01, "DoD Safety and Occupational Health (SOH) Program," October 14, 2014
(g) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 18) – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces During the Coronavirus Disease 2019 Pandemic," March 17, 2021
(h) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic," April 12, 2021

This memorandum updates previous DoD coronavirus disease 2019 (COVID-19) laboratory testing guidance and rescinds and replaces reference (a). This force health protection (FHP) supplement provides guidance on COVID-19 testing for eligible persons suspected of having contracted COVID-19, and applies Centers for Disease Control and Prevention (CDC) testing guidance in the DoD context. DoD Components will continue to employ clinical diagnostic testing[1] in accordance with this guidance. This guidance also supports the DoD surveillance strategy for the COVID-19 pandemic response with complementary health

[1] Testing in this guidance refers to tests that utilize molecular, or when clinically indicated, antigen testing methods.

FHP Supplement 15 Revision 2 – Attachment
Clinical Testing and Case Management – COVID-19[3]

(Based on current CDC guidance[4])

Testing an Individual in a Clinical Setting:

- Test based on clinical judgment and public health considerations.
  - If **laboratory positive:** The individual becomes a COVID-19 case and must be isolated.
  - If **laboratory negative:** The individual should be followed to ensure he/she clinically improves.
    - If **laboratory negative** and asymptomatic or **clinically improved:** The individual has no restrictions.
    - If **laboratory negative** and the individual does **NOT clinically improve or worsens,** and no other etiology is found, then consider re-testing the individual for COVID-19.

Disposition of Laboratory Confirmed or Probable Cases under Isolation:[5]

- **Non-test-based** criteria to discontinue isolation for **symptomatic** persons:[6]
  - At least one day (24 hours) has passed since the last fever without the use of fever-reducing medications; **and**
  - Improvement in symptoms (e.g., cough, shortness of breath); **and**
  - At least 10 days have passed since symptoms first appeared for mild to moderate illness. Note: For persons with severe or critical illness or for severely immunocompromised individuals, discontinue isolation when at least 20 days have passed since symptoms first appeared, in consultation with infectious disease experts.
- **Non-test-based** criteria to discontinue isolation for **asymptomatic** persons not severely immunocompromised (severely immunocompromised individuals should follow the medical guidance of their provider or providers):
  - At least 10 days have passed, without the development of symptoms, since the date of the person's first positive COVID-19 diagnostic test.
  - Follow-on negative testing does not decrease the isolation time frame.
- A **test-based** strategy is **no longer recommended to discontinue isolation**. However, providers may consider using a test-based strategy to discontinue isolation for severely immunocompromised persons, in consultation with infectious disease experts. The test-based criteria are:
  - Resolution of fever without the use of fever-reducing medications;
  - Improvement in symptoms (e.g., cough, shortness of breath); **and**
  - Negative polymerase chain reaction results from at least two **consecutive** respiratory specimens collected at least 24 hours apart.

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[3] This quick reference sheet applies to eligible populations as stated in this guidance.
[4] DoD Components should follow the most current CDC guidance; check for updates regularly.
[5] In locations outside of the United States, host nation policy and guidance should inform disposition of cases.
[6] For additional information and definitions of mild, moderate, severe, and critical illness, and of severely immunocompromised, see the CDC guidance at: **https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html**.

Consolidated Department of Defense Coronavirus Disease 2019 Force Health Protection Guidance – Revision 2

This guidance issued by the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) presents a uniform and consolidated DoD policy for the Department's response to the coronavirus disease 2019 (COVID-19) pandemic and serves as the DoD COVID-19 Workplace Safety Plan.[1] Implementation of this guidance will comply with: 1) applicable court orders, Presidential directives, and Office of Management and Budget (OMB) and Safer Federal Workforce Task Force guidance; and 2) applicable labor obligations to the extent such obligations do not hinder the DoD Components' ability to carry out their missions during this public health emergency. Prior delegations and exceptions made pursuant to the rescinded references remain valid unless rescinded by the authorizing official. Individual sections of this guidance will be updated as necessary by the USD(P&R).

This guidance will be posted, and updated as necessary, at: https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/. DoD Components should monitor this website to obtain the most current version of this guidance. Changes from the previous version will be identified in bold and italics.

Furthermore, this guidance consolidates, incorporates, and rescinds the following policy and guidance:

- Secretary of Defense Memorandum, "Guidance for Commanders' Risk-Based Responses and Implementation of the Health Protection Condition Framework During the Coronavirus Disease 2019 Pandemic," April 29, 2021
- Secretary of Defense Memorandum, "Use of Masks and Other Public Health Measures," February 4, 2021
- Secretary of Defense Memorandum, "Updated Conditions-based Approach to Coronavirus Disease 2019 Personnel Movement and Travel Restrictions." March 15, 2021
- Secretary of Defense Memorandum, "Way Forward for SARS-CoV-2 Testing Within the Department of Defense," April 29, 2021
- Deputy Secretary of Defense Memorandum, "Updated Coronavirus Disease 2019 Guidance Related to Travel and Meetings," September 24, 2021
- Deputy Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of DoD Civilian Employees," October 1, 2021
- Under Secretary of Defense Memorandum, "Administrative Leave for Coronavirus Disease 2019 Vaccination of Department of Defense Employees," April 14, 2021
- Under Secretary of Defense Memorandum, "Force Health Protection Guidance for the Novel Coronavirus," January 30, 2020, and all supplements.
- Under Secretary of Defense Memorandum, "Civilian Personnel Guidance for DoD Components in Responding to Coronavirus Disease 2019," March 8, 2020

[1] Executive Order (EO) 13991, "Protecting the Federal Workforce and Requiring Mask-Wearing," January 20, 2021.

- Under Secretary of Defense Memorandum, "Updated Guidance for Mask and Screening Testing for all Department of Defense Installations and Other Facilities," March 1, 2022

Note: The Deputy Secretary of Defense approved the rescission of listed Deputy Secretary of Defense and Secretary of Defense memoranda and consolidation of these references into this guidance in the Deputy Secretary of Defense Memorandum, "Updated Coronavirus Disease 2019 Guidance Related to Travel and Meetings," September 24, 2021. This September 24, 2021 memorandum authorized the USD(P&R) to rescind memoranda issued by the Secretary of Defense or the Deputy Secretary of Defense for purposes of updating and consolidating force health protection guidance on travel, meetings, or any other COVID-19 personnel- or health-related matter.

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1.2. Authority to Determine HPCON Levels.	August 8, 2022
1.3. Criteria for Changing HPCON Levels.	August 8, 2022
1.4. Workplace Occupancy Levels Within the HPCON Framework.	August 8, 2022
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3.3. Eligibility for DoD Personnel, Other Beneficiaries, and Other Populations for Testing.	April 4, 2022
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Section 7 – Travel	
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7.5. Specific Guidance by Type of Travel.	August 8, 2022
7.6. Additional Guidance for Reserve and National Guard Personnel.	April 4, 2022
7.7. Additional Guidance to Assist Commanders with Travel Decisions.	August 8, 2022
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Section 9 – Definitions	August 8, 2022

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EXECUTIVE SUMMARY

The DoD is committed to providing safe working environments across the entire DoD enterprise, which consists of an approximately 2.9 million-person global workforce deployed or stationed in nearly 150 countries, including military Service members and their families, and DoD civilian and contractor personnel that work in a highly complex and large number of diverse and unique environments. This force health protection (FHP) Guidance ("Guidance") was developed to protect the DoD workforce, contractor personnel, other occupants, and visitors (collectively referred to as "personnel") before, during, and after our orderly and final return to the physical workplace ("final reentry"). The Guidance is intended to meet the direction of the President's EOs[2] and guidance from the Safer Federal Workforce Task Force ("Task Force") and OMB,[3, 4] and articulate steps the DoD has been and will be taking to halt the spread of COVID-19.

Consistent with Task Force and OMB guidance, this Guidance includes policies and procedures that incorporate the best available data and science-based measures and activities that focus on health and safety and on workplace operations. DoD uses the latest guidance from the Centers for Disease Control and Prevention (CDC), and requirements from the Occupational Safety and Health Administration (OSHA) and other relevant Federal agencies as the starting point for developing COVID-19 policy and guidance.

The Department began publishing FHP guidance and policy to address COVID-19 in January 2020. In February 2021, the Secretary of Defense directed the review of all guidance and policy memoranda previously issued for COVID-19.[5] The review was completed in April 2021, and subsequent updates align DoD COVID-19 policy and guidance with current Task Force, OMB, CDC, and OSHA guidance as appropriate.

The DoD COVID-19 Task Force is responsible for recommending updated DoD COVID-19 policy. The Deputy Secretary of Defense and the Vice Chairman of the Joint Chiefs of Staff co-chair the DoD COVID-19 Task Force which assembles as needed for meetings virtually and in person and includes representatives from senior leadership across the Department, including the Secretaries of the Military Departments (MILDEPs), Under Secretaries of Defense, and Combatant Commanders.

DoD has long recognized the threat posed by pandemics and disease outbreaks and has previously issued guidance, planning, and policy documents to prepare for and respond to such threats. The DoD also recognizes that successfully managing the COVID-19 pandemic requires

[2] EO 14042, "Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors," September 9, 2021; EO 14043, "Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees," September 9, 2021.
[3] Documents from the Safer Federal Workforce Task Force are available at: https://www.saferfederalworkforce.gov/overview/.
[4] Office of Management and Budget Memorandum, Office of Personnel Management, and General Services Administration, M-21-25, "Integrating Planning for A Safe Increased Return of Federal Employees and Contractors to Physical Workplaces with Post-Reentry Personnel Policies and Work Environment," June 10, 2021
[5] Secretary of Defense Memorandum, "Strategic Review and Reissuance of All Coronavirus Disease 2019 Policy Documents," February 2, 2021.

the flexibility to adapt to changing conditions (e.g., variants, and disease prevalence or virulence) and new information (e.g., evolving best health and safety practices).

The DoD is committed to protecting its workforce and stakeholders from the effects of the COVID-19 pandemic, while preserving our ability to complete its mission. As data becomes available, science-based evidence emerges, and the CDC, OSHA, and other cognizant agencies, departments, and other elements of the Federal Government revise and develop new recommendations to protect the workforce, the DoD will incorporate them into its current and future policies and guidance as appropriate.

SECTION 1: HEALTH PROTECTION CONDITION (HPCON) FRAMEWORK

1.1. HPCON FRAMEWORK.

Installations[6] will manage COVID-19 health protection measures using HPCON levels. HPCON 0 is the base level for the HPCON Framework and represents a return to normal operations.

Table 1, below, contains FHP activities installation commanders will undertake at each HPCON level. **Installation commanders must change the HPCON level no later than 2 weeks after the CDC Community Level has been elevated and may change the HPCON level 2 weeks after the CDC Community Level has been decreased.** Installation commanders may deem it necessary to take additional precautions for select personnel and medically vulnerable populations (e.g., those who are elderly, have underlying health conditions or respiratory diseases, or are immunocompromised) and are both encouraged and authorized to do so. Installation commanders may further impose additional requirements appropriate for a particular local setting**, operational requirement,** and/or based on transmission risk regardless of HPCON level.

1.2. AUTHORITY TO DETERMINE HPCON LEVELS.

The authority to determine HPCON levels ("HPCON implementation"), **subject to the requirements in section 1.1,** is delegated to the Secretaries of the MILDEPs and Geographic Combatant Commanders and may be further delegated in writing to a level no lower than installation commanders in the grade of O-6 or higher. The Director of Administration and Management (DA&M) has HPCON implementation authority for the Pentagon Reservation, **subject to the requirements in section 1.1. The** Defense Logistics Agency (DLA) has HPCON implementation authority for four locations.[7] ~~**Those with HPCON implementation authority will coordinate changes in HPCON levels with other military installations, affected Geographic Combatant Commands (GCCs), and/or Direct Reporting Units in the same local commuting area (i.e., within approximately 30 miles) to the greatest extent practicable to facilitate consistency in response and unity of messaging.**~~

Geographic Combatant Commanders have authority to determine HPCON implementation policy in accordance with operational requirements, and to match relevant Host

[6] For the purposes of this guidance, a military installation is a base, camp, post, station, yard, center, homeport facility for any ship, or other activity under the jurisdiction of the Secretary of a Military Department or the Secretary of Defense, including any leased facility, which is located within any State, the District of Columbia, the Commonwealth of Puerto Rico, American Samoa, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, or Guam. In the case of an activity in a foreign country, a military installation is any area under the operational control of the Secretary of a Military Department or the Secretary of Defense, without regard to the duration of operational control.

[7] DLA Land & Maritime (Columbus, OH), DLA Distribution HQ (New Cumberland, PA), DLA Aviation (Richmond, VA), and DLA Distribution (San Joaquin, CA).

Nation (HN) and allied forces standards, as applicable. Installation commanders outside the United States have unique geographic constraints and operational considerations for FHP. U.S. personnel should respect relevant HN and allied forces standards, as applicable, and should consult with relevant HN authorities, including public health and medical authorities, when deciding to change HPCON levels.

1.3. CRITERIA FOR CHANGING HPCON LEVELS.

HPCON level determinations for COVID-19 ~~**should be**~~ **are** based on the CDC COVID-19 Community Levels reported by the CDC, [8] which include screening levels that make use of new case-rates and health and health care systems-related information. HPCON Levels A, B, and C correspond directly to CDC COVID-19 Community Levels of low, medium, and high community transmission, respectively.[9]

Installations outside the United States should utilize local community-level data, if available, in setting HPCON levels. Otherwise, installation commanders should consider consulting country-level data for their HN and case-rate information available from the CDC at: https://covid.cdc.gov/covid-data-tracker/#global-counts-rates and the World Health Organization at https://covid19.who.int/. Other sources of data on which installation commanders may rely include academic institutions if such HN data is inaccessible.[10]

Elevation to HPCON D should be based on the determination that there is substantial loss of medical capabilities in the local community. The factors listed in Table 1, below, must be considered when determining whether to move to or from HPCON D.

Table 1, below, includes FHP measures that installation commanders may undertake at each HPCON level, in addition to those required elsewhere in this guidance.

[8] An overview of the CDC COVID-19 Community Levels is available at: https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html.
[9] County Community Levels are available for U.S. States and territories is available at: https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html. Find community levels by "State or Territory" and then by "County or Metro Area." Jurisdictions which are not counties, such as the District of Columbia, also are listed under "County or Metro Area." The Pentagon is in Arlington County, Virginia.
[10] Note: local areas within a country may experience very different COVID-19 case rates than country-specific data.

TABLE 1: Force Health Protection Measures by HPCON Level for the COVID-19 Pandemic

HPCON D Severe	**High COVID-19 Community Level* Risk, with degraded availability of medical countermeasures, and substantial loss of medical capability** **High COVID-19 Community Level* in the county in which the installation is located.** **AND any of the following** **Civilian healthcare capability and utilization (percent and trend)*:** >50 percent staffed of hospital beds filled with individuals who have COVID-19 as the primary admission criteria; or >70 percent of staffed intensive care unit (ICU) beds filled with individuals who have COVID-19 as the primary admission criteria; or Overall staffed hospitals and ICUs have limited to no capacity. **OR** **Military Health System (MHS) health care capability and utilization (percent and trend):** Degradation of MHS capabilities requiring Crisis Status operations; and >95 percent staffed bed occupancy; or >50 percent military medical treatment facility (MTF) staff in isolation or quarantine or unvaccinated; or >60 percent staff absent who provide urgent or emergent care; and Local emergency departments on divert or inability of civilian health care to absorb excess MHS patients; or Clinical or appointment capability reduced >60 percent in key departments. **OR** **Other factors:** Loss of vaccine effectiveness in available vaccines resulting in vaccinated individuals routinely experiencing severe disease, hospitalization or death; or	**Utilize measures from HPCON A, B and C with the following modifications**: a. Less than 25 percent of normal occupancy in the workplace, or the minimum required on-site for essential operations that must be conducted in person. b. Strongly consider declaring a local Public Health Emergency. c. Consider limiting visitor access to the installation to only those required for mission essential activities. d. Cancel non-mission-essential activities. e. Close non-essential services (e.g., fitness centers, leisure and recreational facilities, beauty/barber shops, non-essential retail, dine-in eating establishments). f. Consider potential delay or cancelation of exercises. g. Restrict or suspend social gatherings to the greatest extent possible. h. Follow any other applicable force health protection guidance at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.[11]

[11] For information about masking and screening testing at the various HPCON levels, refer to sections 2.1 and 5.3.

	Elevated case levels resulting in significant curtailment of essential services either on installation or in civilian communities immediately adjacent to the installation (e.g., emergency response, security, facility maintenance, and energy/communication). ***CDC COVID-19 Community Level (by county) can be found at:** https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.html	
HPCON C High	**High COVID-19 Community Level* Risk** **High COVID-19 Community Level* in the county in which the installation is located.** ***CDC COVID-19 Community Level (by county) Civilian county level data can be found at: https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.htm.**	**Utilize measures from HPCON A and B with the following modifications**: a. Less than 50 percent of normal occupancy in the workplace. b. Consider limiting visitor access to the installation for non-essential mission-related/operational activities. c. Limit social gatherings to less than 50 percent facility/room occupancy. d. MTFs may limit elective surgeries in accordance with guidance from the Defense Health Agency and the Assistant Secretary of Defense for Health Affairs. e. Consider re-scoping, modifying, or potentially canceling exercises. f. Indoor common areas and large venues may be closed. Dining establishments may be limited to takeout. g. Gyms may be closed at this level or operate at diminished occupancy. h. Schools operated by the Department of Defense Education Activity (DoDEA) will operate remotely. i. Maximize telework to the greatest extent practical. j. Follow any other applicable force health protection guidance at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.

HPCON B Moderate	**Medium COVID-19 Community level* Risk** **Medium COVID-19 Community Level* in the county in which the installation is located.** ***CDC COVID-19 Community Level (by county) Civilian county level data can be found at: https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.htm.**	**Utilize measures from HPCON A with the following modifications:** a. Less than 80 percent of normal occupancy in the workplace. b. Permit liberal telework where possible, especially for individuals who self-identify as immunocompromised or being at high risk for severe disease. c. Consider limiting occupancy of common areas where personnel are likely to congregate and interact by marking approved sitting areas or removing furniture to maintain physical distancing. d. Follow any other applicable Force Health Protection Guidance at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.
HPCON A Low	**Low COVID-19 Community Level* Risk** **Low COVID-19 Community Level* in the county in which the installation is located.** ***CDC COVID-19 Community Level (by county) Civilian county level data can be found at: https://www.cdc.gov/coronavirus/2019-ncov/your-health/covid-by-county.htm.**	a. Less than 100 percent of normal occupancy in the workplace, with telework as appropriate. b. Communicate to personnel how and when to report illness and seek care for potential influenza-like illness. c. Common areas and large venues (e.g., sit-down dining, movie theaters, gyms, sporting venues, and commissaries) should adhere to established cleaning and sanitation protocols d. DoDEA schools will operate following CDC recommendations and guidelines specific to schools as implemented in operational procedures and guidance from the Director, DoDEA.[12] Children are not required to mask. Any DoD guidance that is more stringent than CDC guidance must be followed. e. Follow any other applicable Force Health Protection Guidance at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.

[12] **https://www.dodea.edu/covid-operations.cfm.**

HPCON 0	**Normal Baseline**	a. Resume routine standard operations. b. Maintain standard precautions such as routine hand washing, cough on sleeve, good diet, exercise, vaccinations, education, routine health alerts, and regular preparedness activities.

1.4. WORKPLACE OCCUPANCY LEVELS WITHIN THE HPCON FRAMEWORK.

Workplace occupancy limits for each HPCON level are included as measures in Table 1. The workplace occupancy levels in ~~**the chart**~~ **Table 1** are ceilings, not goals. Reduced workplace occupancy may be achieved through telework, remote work, flexible scheduling, and other methods, as appropriate. At HPCON A or higher, DoD Components are granted an exception to policy from Enclosure 3, paragraph 3.j.(2) of Department of Defense Instruction 1035.01, "Telework Policy," and may allow DoD civilian employees to telework with a child or other person requiring care or supervision present at home.

DoD Component heads have the authority to grant exemptions for workplace occupancy limits that are required for national security and the success of critical missions. DoD Component heads, other than the Secretaries of the MILDEPs, may delegate this workplace occupancy limit authority in writing to a level no lower than a general/flag officer or Senior Executive Service (SES) member (or equivalent). Secretaries of the MILDEPs may delegate workplace occupancy limit exemption authority in writing to a level no lower than an O-6 installation commander. The DA&M has workplace occupancy limit exemption authority for all DoD Components located on the Pentagon Reservation and other facilities within the National Capital Region managed by Washington Headquarters Services. This authority may be delegated at the discretion of the DA&M. DLA has workplace occupancy limit exemption authority for four locations.[13] When considering a workplace occupancy limit exemption, those with exemption authority must take into account the ability to maintain distance between personnel and other public health and workplace safety measures contained in this Guidance.

A record of all workplace occupancy limit exemptions will be retained by the exemption authority for the duration of the pandemic and until returning to HPCON 0 and provided for awareness to the public health office concerned and to the installation commander, if different from the exemption authority. FHP measures and other appropriate mitigation measures shall be used rigorously in all areas and especially in areas for which an occupancy exemption has been grant.

[13] DLA Land & Maritime (Columbus, OH), DLA Distribution HQ (New Cumberland, PA), DLA Aviation (Richmond, VA), and DLA Distribution (San Joaquin, CA).

SECTION 2: VACCINATION VERIFICATION AND MEASURES BASED ON VACCINATION STATUS

2.1. VACCINATION AND TESTING REQUIREMENTS.

1. Service members:

Service members (members of the Armed Forces under DoD authority on active duty or in the Selected Reserve, including members of the National Guard) are required to be fully vaccinated against COVID-19, subject to any identified contraindications, any administrative or other exemptions established in DoD policy, and any applicable court orders. Service members' vaccination status will be validated utilizing their Military Service-specific Individual Medical Readiness (IMR) system. If a Service member has been vaccinated against COVID-19 outside the military health system, that Service member must show official proof of his or her COVID-19 vaccination status to update the IMR system.

Once the applicable mandatory vaccination date has passed, COVID-19 screening testing is required at least weekly for Service members who are not fully vaccinated, including those who have an exemption request under review or who are exempted from COVID-19 vaccination and are entering a DoD facility located in a county or equivalent jurisdiction where the CDC COVID-19 Community Level is high or medium. Service members who are not on active duty and who also are DoD civilian employees or DoD contractor personnel must follow the applicable requirements in section 2.3 for DoD civilian employees or in section 2.4 for DoD contractor personnel.

2. DoD civilian employees:

Currently, the requirement for all Federal civilian employees to be vaccinated is not in effect. A U.S. district court judge issued a nationwide preliminary injunction prohibiting implementation and enforcement of civilian employee vaccination requirements based on EO 14043. Requirements subject to the injunction and not currently in effect are included in this guidance in a strikeout form for ease of reinstitution by USD(P&R) should the injunction be lifted.

At least weekly COVID-19 testing is required for those DoD civilian employees who are not fully vaccinated when the CDC COVID-19 Community Level is high or medium in the county or equivalent jurisdiction where the DoD facility is located. DoD civilian employees who are not fully vaccinated and who telework or work remotely on a full-time basis are not subject to weekly testing, but must provide a negative result (from a test performed within the prior 72 hours) for entry into a DoD facility located in the county where the COVID-19 Community Level is high or medium**.**

~~To ensure the safety of the DoD workforce,[14] DoD civilian employees are required to be fully vaccinated, unless they have received a temporary or permanent exemption. "DoD civilian employee" includes foreign nationals employed by DoD outside the United States, to the maximum extent possible while respecting host nation agreement and laws. It also includes DoD civilian employees who are engaged in full-time telework or remote work.~~

If they have not already done so, supervisors of DoD civilian employees must ask DoD civilian employees whether they are fully vaccinated. Employees who indicate they are fully vaccinated must provide proof of that vaccination status to their supervisors. Acceptable proof includes:

a. A copy of the COVID-19 Vaccination Record Card (CDC Form MLS-319813_r, published on September 3, 2020);
b. A copy of medical records documenting the vaccination;
c. A copy of immunization records from a public health or State immunization information system; or
d. A copy of any other official documentation containing the data points required to be verified by the supervisor.

When necessary for implementing FHP measures related to workplace access in section 5.5, supervisors of DoD civilian employees may ask DoD civilian employees whether they are up to date with COVID-19 vaccinations. If there is a supervisory concern about the accuracy of the DoD civilian employee's response, DoD civilian employees are required to provide proof of up-to-date vaccination status. Supervisors must not inquire about disabilities when asking DoD civilian employees about up-to-date vaccination status.

~~DoD requires that individuals who started their Government service after November 22, 2021, be fully vaccinated prior to their start date, except in limited circumstances where an accommodation is legally required. However, should DoD have an urgent, mission-critical hiring need to onboard new staff prior to those new staff becoming fully vaccinated, the DoD head may delay the vaccination requirement – in the case of such limited delays, DoD will require new hires to be fully vaccinated within 60 days of their start date and to follow safety protocols for not fully vaccinated individuals until they are fully vaccinated.~~

DoD civilian employees are eligible to receive the COVID-19 vaccine at any DoD vaccination site, including military medical treatment facilities. They may also opt to receive the COVID-19 vaccine at locations other than DoD vaccination sites, such as retail stores, private medical practices, and/or local and State public health department sites.

DoD civilian employees are authorized administrative leave to receive COVID-19 vaccination doses. ~~DoD civilian employees are authorized official duty time to receive COVID-19 vaccination doses, including first, second, and booster shots. For DoD civilian employees who are unable to receive a COVID-19 vaccination within their duty hours, regular overtime rules are applicable.~~ In most circumstances, DoD authorizes employees to take up to 4 hours to

[14] ~~Executive Order 14043, "Requiring Coronavirus Disease 2019 Vaccination for Federal Employees," September 9, 2021.~~

travel to the vaccination site, complete any vaccination dose, and return to work—for example, up to 8 hours of duty time for employees receiving two doses (If an employee needs to spend less time getting the vaccine, only the needed amount of duty time should be granted). Employees taking longer than 4 hours must document the reasons for the additional time (e.g., they may need to travel long distances to get the vaccine). Reasonable transportation costs that are incurred as a result of obtaining the vaccine from a site preapproved by DoD are handled the same way as local travel or temporary duty cost reimbursement is handled based on DoD policy.

DoD civilian employees who experience an adverse reaction to a COVID-19 vaccination should be granted no more than 2 workdays of administrative leave for recovery associated with a single COVID-19 vaccination dose.

DoD will grant leave-eligible employees up to 4 hours of administrative leave per dose to accompany a family member who is receiving any COVID-19 vaccination dose. For example, up to a total of 12 hours of leave for a family member receiving three doses—for each family member the employee accompanies. If an employee needs to spend less time accompanying a family member who is receiving the COVID-19 vaccine, DoD will grant only the needed amount of administrative leave. Employees should obtain advance approval from their supervisor before being permitted to use administrative leave for COVID-19 vaccination purposes. Employees are not credited with administrative leave or overtime work for time spent outside their tour of duty helping a family member get vaccinated.

DoD civilian employees should use the time and attendance code for "physical fitness" to record administrative leave for COVID-19 vaccination recovery time that prevents the employee from working or for taking a family member to be vaccinated for COVID-19) The type hour code is "LN" and the environmental/hazard/other code is "PF." Non-appropriated fund employers should code administrative leave related to COVID-19 in a way that can be easily reported.

3. DoD contractor personnel:

Vaccination requirements for DoD contractor personnel are outlined in several references.[15] In implementing EO 14042, the DoD will comply with all relevant court orders.

Onsite DoD contractor personnel will complete the DD Form 3150, "Contractor Personnel and Visitor Certification of Vaccination";[16] maintain a current completed copy; and show it to authorized DoD personnel upon request when they work at a DoD facility where the CDC COVID-19 Community Level is high or medium. Failure to complete the DD Form 3150 may result in denying DoD contractor personnel access to the DoD facility to which access is sought. Onsite DoD contractor personnel who are not fully vaccinated against COVID-19, because they are not performing under a covered contract that requires COVID-19 vaccination,

[15] Safer Federal Workforce Task Force, "COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors," September 24, 2021; Principal Director for Defense Pricing and Contracting Memorandum, "Class Deviation 2021-O0009-Ensuring Adequate COVID-l9 Safety Protocols for Federal Contractors," October 1, 2021; EO 14042, "Ensuring Adequate COVID Safety Protocols for Federal Contractors," September 9, 2021.
[16] https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd3150.pdf.

due to a legally required accommodation, or who decline to provide information about their COVID-19 vaccination status, will be subject to COVID-19 screening testing at least weekly when the CDC COVID-19 Community Level for the facility in which they work is high or medium. DoD contractor personnel who refuse required COVID-19 screening testing will be denied access to DoD facilities.

For purposes of the requirements regarding providing information about vaccination status and screening testing, "contractor personnel" are those individuals issued a credential by DoD that affords the individual recurring access to DoD facilities, classified herein as "credentialed recurring access" (CRA) (e.g., Common Access Cardholders) who are performing under a contractor or subcontract between their employer and the DoD. "Contractor personnel" do not include employees of DoD contractors or subcontractors receiving ad hoc access to DoD facilities (e.g., delivery personnel, taxi services) or employees of DoD contractors or subcontractors who have access to the grounds of, but not the buildings on, DoD installations (e.g., contract groundskeepers, fuel delivery personnel, household goods transportation personnel).

4. Official visitors:

"Official visitors" are non-DoD individuals seeking access, one time or recurring, in association with the performance of official DoD business (such as to attend a meeting), but who do not have CRA. "Official visitors" do not include personnel receiving ad hoc access to DoD facilities (e.g., delivery personnel, taxi services); individuals who have access to the grounds of, but not the buildings on, DoD installations (e.g., contract groundskeepers, fuel delivery personnel, household goods transportation personnel); personnel accessing DoD buildings unrelated to the performance of DoD business (e.g., residential housing); or personnel accessing DoD facilities to receive a public benefit (e.g., commissary; exchange; public museum; air show; military medical treatment facility; Morale, Welfare and Recreation resources).

Official visitors will complete DD Form 3150; maintain a current completed DD Form 3150; and show it to authorized DoD personnel, upon request when they are visiting a DoD facility where the CDC COVID-19 Community Level is high or medium. Failure to complete the DD Form 3150 may result in denial of an official visitor's access to the DoD facility to which access is sought. Service members not on active duty or active duty for training are also subject to the requirements in this paragraph.

When visiting a DoD facility where the CDC COVID-19 Community Level is high or medium, official visitors who are not fully vaccinated against COVID-19, or who decline to provide information about their vaccination status, must show an electronic or paper copy of negative results from an FDA-authorized or approved COVID-19 test administered no earlier than 72 hours prior to their visit. If unable to show a negative COVID-19 test result, the official visitor may be provided onsite self-testing, if available, or will be denied access to the DoD facility (or facilities) to which access is sought. Service members who are not on active duty or on active duty for training at the time of their official visit are subject to the requirements in this paragraph.

Official visitors will follow applicable DoD policies and procedures, as well as the policies and procedures of the Department or Agency they are visiting, if different from the DoD's. See section 6, below, on Meetings, for how requirements apply to attendees of in-person in meetings, events, and conferences hosted by the DoD.

All official visitors must comply with all applicable FHP guidance.

Currently, the requirement for all Federal civilian employees to be vaccinated is not in effect. A U.S. district court judge issued a nationwide preliminary injunction prohibiting implementation and enforcement of civilian employee vaccination requirements based on EO 14043. Requirements subject to the injunction and not currently in effect are included in this guidance in a strikeout form for ease of reinstitution by USD(P&R) should the injunction be lifted.

~~2.2. ENFORCEMENT OF DOD CIVILIAN EMPLOYEE COVID-19 VACCINATION REQUIREMENT.~~

~~a. DoD civilian employees who refuse to be vaccinated, or to provide proof of vaccination, are subject to disciplinary measures, up to and including removal from Federal service, unless the DoD civilian employee has received an exemption or the DoD civilian employee's timely request for an exemption is pending a decision.~~

~~b. Progressive enforcement actions include, but are not limited, to:~~

~~(1) A 5 calendar-day period of counseling and education;~~
~~(2) A short suspension without pay, generally 14 calendar days or less, with an appropriate notice period. SES members may only be suspended for more than 14 calendar days;~~
~~(3) Removal from Federal service for failing to follow a direct order.~~

~~c. During the notice periods preceding adverse employment actions, DoD civilian employees generally should not be placed on administrative leave. DoD Components should require DoD civilian employees to continue to telework or report to the worksite and follow all mitigation measures applicable to not fully vaccinated DoD civilian employees when reporting to the worksite.~~

~~d. DoD Components will designate officials, at the appropriate organizational level, to handle the disciplinary process to promote consistent application of disciplinary measures. Such officials will decide each case with due regard to the facts and circumstances of that case.~~

~~e. Supervisors should contact their servicing human resources and legal offices to discuss options available to address individual situations regarding enforcement of this requirement.~~

f. DoD Components are encouraged to identify an occupational health office, medical office, or other resource with which a DoD civilian employee may consult during the period of counseling and education.

2.3. EXEMPTIONS FROM DOD CIVILIAN EMPLOYEE COVID-19 VACCINATION REQUIREMENT.

a. DoD civilian employees may request an exemption on the basis of a medical condition or circumstance or a sincerely held religious belief, practice or observance. Because all DoD civilian employees must now be vaccinated against COVID-19 as a condition of employment, exemptions will be granted in limited circumstances and only where legally required. The information collected must be handled in accordance with the privacy requirements in section 8.

b. Personnel.

(i) Decision Authority. Management official(s) will be designated to serve as Decision Authorities to make decisions concerning requests for exemption from the COVID-19 vaccination requirement, in consultation with the organization's servicing legal office. Decision Authorities will be at an appropriate level within the organization to consider the impact, if any, that granting a request will have on the DoD Component operations and to promote similar cases being handled in a consistent manner, with due regard for the facts and circumstances of each case. Each employee's request must be considered on its own merits.

(ii) Subject Matter Experts. DoD Components may identify subject matter experts in areas such as human resources (HR), equal employment opportunity (EEO), medicine, and religious matters to serve as advisors to assist Decision Authorities. Such advisors may provide individual advice, as needed by the Decision Authority, but may not be used to develop a group or consensus recommendation or decision.

(iii) Administrative Support. DoD Components will provide appropriate personnel and other resources to administratively support the Decision Authorities, including support necessary to assist the Decision Authorities with preparing written products.

c. Employee Notice. DoD Components will inform DoD civilian employees how to make a request for an exemption. Requests needed to have been submitted no later than November 8, 2021, absent extenuating circumstances, to be considered timely.

d. Employee Requests. To make a request for exemption from the COVID-19 vaccination requirement, DoD civilian employees must submit a request to their direct supervisor. For purposes of submitting this exemption request, "direct supervisor" includes an authorized human resources official. The employee must provide an official statement which describes the medical or religious reason the employee objects to vaccination against COVID-19. Generally, such requests must be in writing. DoD civilian employees may use DD Form 3176 or DD Form 3177 to submit their requests. DoD civilian employees who make oral requests may be provided a sample written request format and/or be interviewed to develop the basis for the

request. While the use of the DD Form 3176 and DD Form 3177 is optional for DoD civilian employees, when DoD civilian employees make a request, they must provide the following information:

(1) Medical Exemption Requests.

- A description of the medical condition or circumstance that is the basis for the request for a medical exemption from the COVID-19 vaccination requirement;
- An explanation of why the medical condition or circumstance prevents the employee from being safely vaccinated against COVID-19;
- If it is a temporary medical condition or circumstance, a statement concerning when it will no longer be a medical necessity to delay vaccination against COVID-19; and
- Any additional information, including medical documentation that addresses the employee's particular medical condition or circumstance, which may be helpful in resolving the employee's request for a medical exemption from the COVID-19 vaccination requirement.

(2) Religious.

- A description of the religious belief, practice, or observance that is the basis for the request for a religious exemption from the COVID-19 vaccination requirement;
- A description of when and how the DoD civilian employee came to hold the religious belief or observe the religious practice;
- A description of how the DoD civilian employee has demonstrated the religious belief or observed the religious practice in the past;
- An explanation of how the COVID-19 vaccine conflicts with the religious belief, practice, or observance;
- A statement concerning whether the DoD civilian employee has previously raised an objection to a vaccination, medical treatment, or medicine based on a religious belief or practice. If so, a description of the circumstances, timing, and resolution of the matter; and
- Any additional information that may be helpful in resolving the DoD civilian employee's request for a religious exemption from the COVID-19 vaccination requirement.

e. Supervisor Responsibilities.

(i) Following receipt of an employee's request for exemption, supervisors must update Section B of the employee's DD Form 3175 to indicate that a request for exemption determination is pending.

(ii) As necessary, supervisors will engage with the employee to ensure completeness of the employee's exemption request.

(iii) In coordination with human resources officials, supervisors will prepare an exemption request package that contains factual information about the circumstances of the employee's request. A complete exemption request package will include the basis for the employee's request and any supporting documentation submitted by the employee, a description of the nature of the employee's job responsibilities and work environment, and any circumstances relevant to a management-level assessment of the reasonably foreseeable effects on the agency's operations, including protecting the agency's workforce and members of the public with whom the employee interacts in the workplace from COVID-19, if the employee remains unvaccinated.

(iv) Supervisors will forward the exemption request package to the Decision Authority Support Office.

f. Decision Authority Support Office.

(i) DoD Components will establish Decision Authority Support Offices to support exemption request Decision Authorities.

(ii) The Decision Authority Support Office will intake exemption request packages and, under the supervision of the Decision Authority, provide administrative support to the Decision Authority.

(iii) At the request of the Decision Authority, the Decision Authority Support Office may coordinate with subject matter experts to obtain written documentation which includes relevant factual information and, as necessary, a professional opinion related to the factual information, for inclusion in the exemption request package.

(iv) The Decision Authority Support Office may not provide a consensus opinion or recommendation to the Decision Authority.

g. Decision Authority Determination.

(i) The Decision Authority first analyzes the exemption request package. As necessary, the Decision Authority may request additional information and consult with subject matter experts.

(ii) After conducting a review of the exemption request, the Decision Authority makes a determination, prepares a written statement that includes the reasons for the determination (which may involve drafting assistance based on the Decision Authority's instructions regarding its contents), and obtains a legal review of the determination.

(iii) In cases where the exemption is temporary or denied, the Decision Authority's determination must specify a date by which the DoD civilian employee must be fully vaccinated against COVID-19. In specifying that date, DoD civilian employees must be given a minimum period of 14 days to receive their first (or only) dose of a COVID-19 vaccine.

h. Employee Notification of Determination. The Decision Authority Support Office will transmit the Decision Authority's written determination to the DoD civilian employee's supervisor, who, in turn, provides the DoD civilian employee with a copy of the written determination, updates the DD Form 3175, and informs the DoD civilian employee of next steps.

i. A chart illustrating the exemption request process is below.

Position	**Role/Responsibility**	**Output**	**Submit to**
Requesting employee	Provide vaccination status via DD Form 3175 to indicate exemption pending.	Completed DD Form 3175.	Supervisor
Requesting employee	Request exemption.	Completed DD Form 3176 (medical) or DD Form 3177 (religious), as appropriate, or other request that contains the information required by FHP 23, Revision 3.	Supervisor
Supervisor, in consultation with HR officials	Provide relevant information concerning employee's occupation and work environment, including: availability of measures to physically distance requestor from co-workers and members of the public, the volume of exemption requests in the organization, and any other relevant information concerning the circumstances of the employee's request.	Exemption request package that includes employee's request and supervisory information concerning employee's occupation, work environment, and other circumstances of the request.	Decision Authority Support Office
Decision Authority Support Office	Receive and track processing of exemption request package. Supplement	Exemption request package that includes employee's request; supervisor	Decision Authority

	~~package with individual advice from subject matter experts and relevant factual information, as directed by the Decision Authority.~~	~~information concerning employee's occupation, work environment, and other circumstances of the request; and any supporting documentation relevant to the Decision Authority's analysis.~~	
~~Decision Authority~~	~~Review submitted documentation, request any reasonably necessary additional information, and prepare written decision in consultation with legal advisors and with the advice of subject matter experts, as appropriate.~~	~~Written decision that addresses employee's individual circumstances and has been reviewed by appropriate legal advisors.~~	~~Supervisor~~
~~Supervisor~~	~~Receive decision, discuss with employee. If exemption approved, implement mitigation measures and, if necessary, address any follow-on requests for accommodation in accordance with Component EEO procedures. If disapproved, provide opportunity for counseling by medical professional or other appropriate expert/ initiate requirement for~~	~~If approved, employee continues to comply with generally-applicable mitigation measures (for instance, as applicable, screening testing, masking, and physical distancing) and any other mitigation measures directed by the Decision Authority or management officials. If disapproved, vaccination tracking and/or progressive discipline.~~	~~Employee~~

	~~vaccination. Work with the legal advisor(s) and, as appropriate, HR LMER and EEO offices.~~		

~~j. Exemption Criteria.~~

~~(i) Religious Exemption Requests. Requests for religious exemption will be analyzed pursuant to the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. § 2000bb et seq. RFRA prohibits the Government from substantially burdening a person's exercise of religion, unless it demonstrates that application of the burden to the person is in furtherance of a compelling governmental interest and is the least restrictive means of furthering that compelling governmental interest. In the first instance, Decision Authorities are to determine whether the requestor has met his or her burden to establish that the vaccination requirement imposes a substantial burden on exercise of a sincerely held religious belief. If so, Decision Authorities analyze the request to determine whether the burden on religious exercise is the least restrictive means of furthering the Government's compelling interest in health and safety of the DoD workforce, and the health and safety of members of the public with whom they interact. If vaccination is not the least restrictive means, the exemption will be granted and supervisors will implement the less restrictive means.~~

~~(ii) Medical Exemption Requests. Pursuant to the Rehabilitation Act of 1973, as amended, 29 U.S.C. § 791 et seq. Decision Authorities will analyze requests for medical exemption to determine whether the medical condition or circumstance prevents the employee from safely being vaccinated. If so, the employee will be exempt from vaccination (temporarily or permanently, as appropriate). Supervisors will direct compliance with applicable FHP guidance and direct any mitigation measures that are necessary to prevent the spread of the virus that causes COVID-19 in the workplace and to the members of the public with whom the employee interacts. If such measures result in the employee being unable to perform the essential functions of the position, such matters will be referred to the equal employment opportunity reasonable accommodation process.~~

~~k. Additional Guidance.~~

~~(i) Information collected concerning medical and religious exemption requests must be maintained in accordance with the privacy requirements in section 8. Requests for medical exemption will be treated as medical records to be maintained separately from other personnel files.~~

~~(ii) Discipline for failure to meet the COVID-19 vaccination requirement will not be initiated against a DoD civilian employee while a request for a medical or religious exemption from the COVID-19 vaccination requirement is pending determination. If a DoD civilian employee submits a request after discipline is initiated, disciplinary measures may be held in abeyance where appropriate.~~

~~(iii) DoD civilian employees who are not fully vaccinated but who have a pending request for exemption from vaccination are required to comply with any mitigation measures that~~

~~are applicable to all DoD civilian employees in the worksite who are not fully vaccinated. Requests for reasonable accommodation related to those mitigation measures will be combined with any pending medical or religious exemption to vaccination request, for purposes of making a final determination concerning those measures. Without making a finding concerning whether a sufficient basis for a reasonable accommodation concerning those measures exists, the supervisor may use the normal interactive process to pursue a temporary accommodation that protects the health and safety of the workplace while a decision concerning those measures is pending. Otherwise, requests for reasonable accommodation related to force health protection and mitigation measures may be analyzed separately from requests for exemption from vaccination.~~

~~(iv) A DoD civilian employee who receives an exemption from the vaccination requirement may, because of the exemption, be unable to perform the duties and responsibilities of the position without a change in working conditions. Supervisors will immediately implement any mitigation measures required by the Decision Authority and applicable FHP guidance. Supervisors may engage in the normal interactive process concerning any other measures necessary to protect the health and safety of the workplace.~~

~~(v) Requests for exemption from candidates for employment will be handled consistent with the procedures in this section.~~

~~(vi) Unless responsibility is otherwise established in a written support agreement, the Combatant Command Support Agent identified in DoD Directive 5100.03, "Support of the Headquarters of Combatant and Subordinate Unified Command," is responsible for administration of exemption processes applicable to DoD employees assigned, detailed, or otherwise deployed to a Combatant Command area of responsibility.~~

SECTION 3: CONDUCTING TESTING FOR SUSPECTED COVID-19 CASES AND GENERAL ELIGIBILITY FOR DOD-CONDUCTED TESTING

This section provides guidance on COVID-19 testing for eligible persons suspected of having contracted COVID-19.

3.1. TESTING CONSIDERATIONS.

Health care providers will use their clinical judgment and awareness of laboratory testing resource availability, and will work closely with local and installation public health authorities or Public Health Emergency officers, to guide COVID-19 diagnostic testing. Providers are encouraged to test for other causes of respiratory illness as clinically indicated. The CDC testing priorities may be found at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing.html.

Asymptomatic individuals may be tested based on a clinician's judgment and as deemed appropriate by public health professionals and in accordance with current guidance.

DoD Components must ensure appropriate infection prevention and control procedures are followed throughout the entire testing process. This includes employing the appropriate biosafety precautions when collecting and handling specimens, consistent with CDC guidance.

3.2. DOD LABORATORIES AND TESTS.

The DoD is committed to maximizing testing capability for operational needs and to increasing standardization and synchronization of testing across the Department. However, differences among operational environments, deployment cycles, and congregate setting limitations drive differences in testing demands to mitigate operational risk. This testing includes molecular tests and, for certain limited circumstances, alternative options such as serial ***rapid*** antigen testing.

DoD Components will ensure that diagnostic testing and screening testing **performed by laboratories within the Military Health System** are conducted at laboratories designated by the Defense Health Agency's (DHA) Center for Laboratory Medicine Services (CLMS). CLMS manages diagnostic and screening testing policy, certification, and exceptions in accordance with current guidance. CLMS may be contacted at: dha.ncr.clinic-support.mbx.clms@mail.mil.

DoD Components must comply with Food and Drug Administration (FDA) regulations for diagnostic testing and screening testing, including by complying with COVID-19 emergency use authorizations (EUAs) or biologics license applications (BLAs), and other current guidance. The FDA COVID-19 EUA list is available at: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

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DoD Components may consider non-clinical, Research Use Only molecular tests[17] for surveillance testing using a pooled specimen testing protocol, consistent with applicable law and regulations. Results from any positive pools will only be reported in aggregate and must not be placed into any individual's medical record. Any positive pool must be followed by testing every individual sample in that pool with an FDA EUA-authorized molecular test, or an FDA-EUA or BLA authorized test (when available), and performed in a clinical laboratory registered by CLMS, or an equivalent civilian laboratory.

FDA EUA-authorized diagnostic and screening tests that are authorized for pooled testing for screening testing purposes may be performed at Clinical Laboratory Improvement Program-registered laboratories, in accordance with the terms of the applicable EUA.

DoD Components must coordinate planned updates to pooled testing protocols with the Assistant Secretary of Defense for Health Affairs (ASD(HA)). The Secretaries of MILDEPs will retain authority to prioritize pooled testing populations and assignments to MILDEP pooled testing laboratories and resources.

DoD Components are encouraged to employ next-generation sequencing (NGS) technology for COVID-19 surveillance testing. As with testing completed via pooled testing, testing requirements using NGS must be coordinated with the ASD(HA).

DoD Components must record COVID-19 diagnostic and screening testing results in the electronic health record or occupational health record of the individual tested in accordance with Department of Defense Instruction (DoDI) 6040.45, "DoD Health Record Life Cycle Management," and applicable processes for DoD contractor personnel. DHA will assist DoD Components, as needed, to ensure this occurs.

3.3. ELIGIBILITY OF DOD PERSONNEL, OTHER BENEFICIARIES, AND OTHER POPULATIONS FOR TESTING.

DoD Components may test Service members (including members of the Reserve Components when on active duty for a period of more than 30 days, or on full-time National Guard duty of more than 30 days) suspected of having contracted COVID-19, for purposes of disease surveillance, and for official travel in accordance with this guidance. Reserve Component Service members on active duty for a period of 30 days or less will follow their Component's guidelines.

DoD civilian employees (who are not otherwise DoD health care beneficiaries) suspected of having contracted COVID-19 may be offered screening testing if their supervisor has determined that their presence in the DoD workplace or official travel is required. DoD civilian employees may also be offered screening testing in connection with workplace disease surveillance.

[17] Research Use Only assays are products in the laboratory research phase of development and are not approved for clinical diagnostic use (https://www.fda.gov/media/87374/download).

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DoD contractor personnel suspected of having contracted COVID-19, or for whom testing is required for workplace surveillance or official travel, may be offered screening testing, subject to available funding, if such testing is necessary to support mission requirements and is consistent with applicable contracts. For example, if testing is explicitly called for under the contract; or if testing is required to access a DoD facility and the contractor personnel must access the DoD facility to perform under the contract. DoD contracting officers may also modify existing contracts to require contractors to test their personnel, or to permit DoD to test their personnel, as necessary to support mission requirements and subject to available funding.

For testing of foreign national employees in locations outside the United States who are suspected of having contracted COVID-19, DoD Components should refer to country-specific labor agreements or contracts and consult with supporting legal counsel for guidance and any limitations concerning such tests.

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SECTION 4: SURVEILLANCE AND SCREENING TESTING

4.1. CONDUCTING REQUIRED SCREENING TESTING.

To establish COVID-19 screening testing for individuals for whom weekly screening testing is required, DoD Components will:

a. Execute the screening testing requirement with FDA approved or authorized COVID-19 self-collection kits or self-tests at least weekly (depending on the type of test kit used). Testing should be performed primarily onsite at the installation or facility with proper supervision and documentation of testing results. If onsite COVID-19 screening testing is not feasible, as an alternative self-testing may be performed at home or in other locations. (Note: these COVID-19 self-tests do not require a health care provider's clinical care order and are, therefore, considered an over-the-counter test and do not require medical support to complete).

    1. COVID-19 self-tests must have Instructions for Use and FDA approval, 510(k) premarket clearance or have an FDA EUA. These tests will be made available through the DLA.

    2. Funding for COVID-19 screening testing, if self-collection kits or self-tests are not available:

        i. Each DoD Component will reimburse Service members and DoD civilian employees for COVID-19 screening tests that require payment for purposes of meeting the screening testing requirement (e.g., if the screening test is not available through the DoD Component and must be administered by a facility who charges for the test).

        ii. For COVID-19 screening testing of DoD contractor personnel with CRA, DoD Components will offer, if available, COVID-19 screening testing similar to that offered to DoD civilian employees at the DoD Component's expense and at no cost to the contractor personnel or the contractor.

b. Establish guidance for where and how these tests will be distributed and conducted, and how results are to be reported.

    1. DoD civilian employees are responsible for providing documentation of negative COVID-19 test results, upon receipt, to the appropriate supervisor. For purposes of screening testing requirements, "supervisor" includes authorized human resources officials. DoD civilian employees may not be required to use their own personal equipment for the purpose of documenting test results; offsite tests may not be used if there is not a means to document results using Government equipment. The supervisor is responsible for maintaining any COVID-19 test results provided by DoD civilian employees in accordance with the privacy protection measures in section 8.

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2. DoD contractor personnel with CRA will maintain their most recent COVID-19 test result and show the result to authorized DoD personnel upon request.

c. After COVID-19 screening testing procedures are established, personnel subject to screening testing are required to have a negative COVID-19 screening test result for entry into a DoD facility. DoD Components may bar DoD civilian employees who refuse required screening testing from their worksites on the installation or facility to protect the safety of others. If the COVID-19 screening test is administered offsite, the negative result must be from a test performed within the prior 72 hours. If a COVID-19 screening test is administered onsite, the test will be administered before DoD civilian employees and contractor personnel go to their work areas. Personnel who have tested positive for COVID-19 are exempted from regular screening testing for 90 days following the documented date of their initial positive test of COVID-19. Documented proof of this positive test date shall be provided upon request.

d. DoD civilian employees and DoD contractor personnel with CRA with positive COVID-19 screening tests will be offered, but not required to take, FDA approved or authorized confirmatory laboratory-based molecular (i.e., polymerase chain reaction) testing paid for by the relevant DoD Component. Contact tracing and mitigation measures will be conducted in accordance with sections 4.4 and 5.5. If the confirmatory test is negative, the individual is not considered to be COVID-19 positive and will be allowed into the workplace.

e. For DoD civilian employees, COVID-19 screening testing is expected to take no more than 1 hour of regular duty time, per test, to complete required testing as directed by the DoD Component. Laboratory-based confirmatory COVID-19 testing for initial positive screening test results is expected to take no more than 2 hours of duty time. This includes time for travel to the testing site, time to complete testing, and time to return to work. Commanders and supervisors will monitor duty time usage and keep duty time used for testing within these parameters to the extent possible.

f. A religious or medical exemption from COVID-19 vaccination is not an exemption from required COVID-19 screening testing. If a DoD civilian employee requires a religious or medical exemption from participation in COVID-19 screening tests, DoD Components should follow existing processes to determine if an appropriate flexibility or accommodation may be provided.

4.2. HEALTH SURVEILLANCE ACTIVITIES.

To assess the threat and inform our understanding of COVID-19 transmission, DoD Components will continue to employ existing syndromic, respiratory, and COVID-19 surveillance programs and efforts. **Appropriate** DoD Components will continue, and expand as feasible, the following core surveillance activities:

- Syndromic surveillance through the Electronic Surveillance System for Early

Notification of Community-based Epidemics to monitor for COVID-19-like illness.

- Respiratory surveillance testing of samples occurring at sites participating in the DoD Global Respiratory Pathogen Surveillance program for influenza-like-illness, including COVID-19.

- Surveillance for acute or febrile respiratory diseases or illnesses at initial entry training sites, with data collection and reporting in accordance with DoD Component testing plans.

- Clinical diagnoses of COVID-19 cases identified in military medical treatment facilities and reported through case-based surveillance in the Disease Reporting System-internet.

- Contact tracing of confirmed COVID-19 positive cases to infected persons in accordance with all applicable Federal, State, local, and DoD requirements.

- Continued reporting of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)/COVID-19 test results in accordance with all applicable Federal, State, local, and DoD requirements, and as appropriate, to respect HN guidelines.

- Expansion of whole genome sequencing efforts for respiratory surveillance testing with a focus on variants of concern[18] and interest to the DoD, and cases of re-infection and infection in vaccinated individuals (i.e., "vaccine breakthroughs"). Sequencing efforts are led by the Global Emerging Infections Surveillance Program (dha.ncr.health-surv.mbx.promis@mail.mil).

- Leverage alternative technologies, such as wastewater surveillance, to supplement existing COVID-19 surveillance systems as a capability that provides an efficient pooled community sample to understand more fully the extent of COVID-19 infections in communities.

4.3. METHODS FOR OPERATIONAL RISK REDUCTION.

- DoD Components may perform COVID-19 testing of asymptomatic DoD personnel prior to deployment or redeployment and may perform COVID-19 tests prior to start of Service member training, as determined appropriate by the medical staff and approved by the commander or supervisor, in accordance with DoD Component plans.

- DoD Components will ensure DoD personnel who are tested using a screening testing protocol are notified of their test results.

[18] The President's "National Strategy for the COVID-19 Response and Pandemic Preparedness," January 21, 2021.

- Symptomatic DoD personnel will be managed in accordance with current guidance.

- DoD Components may, in consultation with public health advisors, conduct screening testing of Service members to reduce risk in congregate settings, on ships, at training sites, during events, or in remote locations where early identification, isolation, and quarantine are important. Screening testing protocols may involve testing of all Service members prior to participation in an event (such as an exercise or training evolution) with or without testing during the event. Finally, screening testing may be performed using a surveillance protocol in which a specified percentage of randomly selected Service members are tested during regular intervals over a period of heightened vulnerability such as when case rates are very high or medical resources are in high demand.

- Voluntary testing of eligible family members, DoD civilian employees, and DoD contractor personnel (if appropriate and permitted in accordance with applicable contracts) who, if infected with COVID-19, could impact the DoD workforce and missions, may be conducted in support of the DoD's effort to interrupt transmission of the virus among our populations. Testing will be conducted based on availability and managed at the DoD Component level.

4.4. COVID-19 CONTACT TRACING AND TESTING.

DoD Components will conduct contact tracing on all COVID-19 cases identified through testing activities **and prioritize investigation of COVID-19 cases, clusters, and outbreaks involving high-risk congregate settings, unusual clusters of cases, and considered for novel or emerging variants that pose a significant risk for severe disease, hospitalization, or death.** Follow-on quarantine or isolation measures and testing will be implemented as indicated.

SECTION 5: PROTECTING PERSONNEL

5.1. GENERAL MEASURES FOR PERSONNEL.

a. Personnel should frequently wash hands with soap and water for at least 20 seconds. When soap and running water are not available, they should use an alcohol-based hand sanitizer, with at least 60-percent ethanol or 70-percent isopropanol as active ingredients, and rub their hands together until they are dry. In addition, personnel should be advised to:

- Avoid touching their eyes, nose, or mouth with unwashed hands.
- Cover coughs and sneezes or cough/sneeze into the inside of elbows/upper sleeve.
- Avoid close contact (within 6 feet of any individual for a total of 15 minutes or more over a 24-hour period) with people.
- ~~**Stay home if**~~ **Self-screen for COVID-19 symptoms[19] before entering a DoD facility or interacting with members of the public in person as part of your official duties. Stay home if you have symptoms or feel** sick, including "not feeling well," or "start of a cold or allergies," and similar circumstances.
- Recognize personal risk factors. According to the CDC, certain people, including older adults and those with underlying conditions such as cancer, heart or lung disease, chronic kidney disease requiring dialysis, liver disease, diabetes, immune deficiencies, or obesity, are at higher risk for developing more serious complications from COVID-19. See additional information on the CDC website at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.
- Launder or replace masks regularly to promote good hygiene.
- To prevent the spread of COVID-19 in elevators, take the stairs when possible.
- Regularly disinfect surfaces commonly touched by others such as touch screens, mice, and desktops with an alcohol or germicidal wipe as described in section 5.8.

b. Installations will post signage about specific measures applicable to the installation, such as mask wearing and physical distancing requirements, and on installation websites, as appropriate.

5.2. PHYSICAL DISTANCING.

Supervisors will maintain at least six feet of separation between individuals in DoD workplaces whenever possible and regardless of the CDC COVID-19 Community Levels. **This requirement does not apply to students in DoD schools.** Installation commanders will implement measures designed to ensure at least six feet of separation in indoor areas whenever possible (including common areas, elevators, stairs, and escalators) and outdoor areas which are crowded or in which personnel are required to congregate, such as building entrances and security checkpoints.

[19] COVID-19 symptoms can be found at: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

Supervisors will limit requirements for face to face interactions in circumstances when physical distance cannot be maintained and will consider use of telecommunication tools even when onsite.

Installation commanders will determine whether stairwells or sides of stairwells should be designated as "up" and "down" to promote physical distancing. Installation commanders will consider placing signs limiting the number of personnel allowed inside elevators and use floor markings showing where personnel should stand in elevator lobbies and within elevators to reinforce physical distancing.

5.3. MASKS.

a. The following masking guidance applies to all DoD installations and other facilities owned, leased, or otherwise controlled by the DoD:

- When the CDC COVID-19 Community Level[20] is high in the county or equivalent jurisdiction where a DoD installation or facility is located, indoor mask-wearing is required for all individuals, including Service members, DoD civilian employees, onsite DoD contractor personnel (collectively, "DoD personnel"), and visitors, regardless of vaccination status.

- When the CDC COVID-19 Community Level is medium or low in the county where a DoD installation or facility is located, indoor mask-wearing is not required.

- Individuals may choose to wear a mask regardless of the COVID-19 Community Level.

b. Exceptions to mask wearing are limited to:

1. When an individual is alone in an office with a closed door and floor-to-ceiling walls;
2. Brief periods of time when eating and drinking while maintaining distancing and in accordance with instructions from commanders and supervisors;
3. When the mask is required to be lowered briefly for identification or security purposes;
4. When necessary as a reasonable accommodation for a person with a disability or to reasonably accommodate participation in a religious service;
5. When clear or unrestricted visualization of verbal communication is required for safe and effective operations (e.g., air traffic control, emergency dispatch, police/fire/emergency services);
6. When the person who would be wearing the mask is under the age of two, sleeping, unconscious, incapacitated, or otherwise unable to remove the mask without assistance;

[20] See section 1.3 for information about CDC COVID-19 Community Levels.

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7. When engaged in training in which mask wearing is not feasible or creates a hazard, such as swim qualification, amphibious, and aquatic training events;
8. When individuals are alone (or with members of their household or close social pod) in their housing, private outdoor space, or personally owned vehicle;
9. When personnel are operating machinery, tools, and/or other items during the use of which a mask would present a safety hazard (for example, the use of a gaiter may be needed for flight line safety reasons);
10. When environmental conditions are such that mask wearing presents a health and safety hazard (e.g., extreme elevated temperatures); and
11. When individuals are enrolled in a respiratory protection program and are wearing a respirator during the performance of duties requiring respiratory protection.

c. Case-by-case exceptions to the requirements for mask wearing as determined at a level no lower than a general/flag officer in the grade of O-7, SES member (or equivalent), or, for installations that do not have officials at these levels, O-6 installation commanders.

d. Transportation: All individuals~~, regardless of vaccination status,~~ must wear a mask on DoD ~~transportation assets (e.g., planes, water transport, buses, trains, taxis, and ride-shares)~~ **aircraft, boats and other maritime conveyances, and buses** traveling into, within, or out of the United States, and indoor DoD transportation hubs**, regardless of vaccination status and the CDC COVID-19 Community Levels.** Masks are ~~not required~~ **optional** in outdoor areas of **these** conveyances (if such outdoor areas exist on the conveyance) or while outdoors at transportation hubs, if these areas are uncrowded. ~~These~~ **Masking** requirements apply whether the DoD ~~transportation assets and hubs~~ **aircraft, boats and other maritime conveyances, and buses** are located inside or outside the United States, but exclude ~~ships, submarines, aircraft,~~ **these conveyances** and other tactical vehicles and craft in their operational environment. ~~Individuals~~ **It is recommended that individuals** ~~will~~ wear a mask in Government cars, vans, or other low occupancy transportation assets**, regardless of** ~~in areas where~~ the CDC COVID-19 Community Level ~~is high when traveling with others. Masks are optional in areas where the CDC COVID-19 Community Level is low or medium for all individuals if traveling in Government low occupancy transportation~~**.**

e. Notwithstanding the above, **and regardless of the CDC Community Level,** masks must be worn by personnel working in DoD health care facilities (including military medical, dental, and veterinary treatment facilities) in accordance with requirements specified in 29 CFR § 1910.502 and in accordance with OSHA and CDC guidelines. Masks will be worn by visitors and patients to DoD military medical and dental treatment facilities except while undergoing medical examinations or procedures that interfere with those activities.

f. Each installation and other facility will post signage regarding mask-wearing and physical distancing requirements. Such signage may vary as needed given local requirements and conditions. Information about these requirements at specific installations and other facilities should be publicly available on website(s) and regularly communicated to all personnel.

5.4. CASE MANAGEMENT AND RESTRICTING WORKPLACE ACCESS – SERVICE MEMBERS.

Testing of Service members:

- Test based on clinical judgment and public health considerations.
  - If laboratory positive: The Service member becomes a COVID-19 case and must be isolated.
    - The Service member will stay isolated for 5 days (day 0 is the day symptoms started or date of specimen collection if asymptomatic).
    - The Service member may leave isolation after 5 days, if no symptoms are present or if he/she is afebrile for more than 24 hours and any remaining symptoms are resolving. Mask wearing must continue for 5 days after leaving isolation when around others, even if mask wearing is not otherwise required by DoD guidance.
    - If fever, shortness of breath, or severe fatigue start or persist, the Service member will stay isolated until these symptoms resolve. The Service member should be seen and managed by medical personnel.
    - A negative test is not required to discontinue isolation due to difficulty interpreting persistent positive results. This is consistent with the CDC's recommendation to NOT test during the 90-day period following initial diagnosis. This applies to all viral testing methodologies, including antigen testing.
  - If laboratory negative: The Service member should be followed to ensure he/she clinically improves.
    - If laboratory negative and asymptomatic or clinically improved: The Service member has no restrictions.
    - If laboratory negative and the Service member does NOT clinically improve or worsens, and no other etiology is found, then consider re-testing for COVID-19.

Management of Close Contacts of a Case (as determined by contact tracing):[21]

- ~~**When the close contact is a Service member fully vaccinated**~~ **Quarantine is not required for Service members who are close contacts and who are up-to-date** with an FDA licensed or authorized COVID-19 vaccine, or a World Health Organization Emergency Use Listing COVID-19 vaccine~~**, quarantine is required unless the individual has: (1) received an FDA licensed or authorized COVID-19 booster dose; (2) it has been less than 5 months since completion of the primary series with an mRNA vaccine (i.e., Pfizer-BioNTech/Comirnaty or Moderna/Spikevax); or (3) it has been less than 2 months since receiving a Johnson and Johnson COVID-19 vaccine dose as a primary vaccination.**~~ Regardless of vaccination status, close contacts must wear a mask around others for 10 days, even if mask wearing is not otherwise required by DoD guidance, and if practical, test on day 5 following exposure. If symptoms develop, then the individual must get tested and isolate until test results are complete.
- Close contact Service members who are not ~~**fully vaccinated**~~ **up-to-date with the COVID-19 vaccine** must quarantine for 5 days. The Service member should wear a mask

[21] For more information on contact tracing with respect to Service members, see: https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/contact-tracing.html.

at all times when around other individuals, regardless of those individuals' vaccination status, and even if mask wearing is not otherwise required by DoD guidance. Testing should occur on day 5 after exposure~~**, if practical**~~**.** If no symptoms develop, quarantine may end after 5 days, but the Service member must continue to wear a mask around others for an additional 5 days (i.e., masks must be worn for a total of 10 days after exposure, including the time in quarantine). If any symptoms develop at any time, the individual should be tested for COVID-19 and advised to isolate.

- Exceptions to the above protocols for asymptomatic Service members with potential exposure based on close contact who are not fully vaccinated, and whose presence is required in the workplace, may be considered in cases of mission-essential activities that must be conducted on site. This exception may be granted in writing by the first general/flag officer, SES member, or equivalent, in the chain of command/chain of supervision or, for those locations that do not have general/flag officers or SES leaders, by O-6 installation commanders. Vaccination status of the Service member should be considered in granting an exception, as more risk will be assumed in granting an exception for a Service member who is not fully vaccinated. Service members who develop signs or symptoms consistent with COVID-19 during the duty period, he/she will be ordered to return to quarters and provided instructions for compliance with this guidance. Service members granted an exception must comply with the following practices for 5 days after the last exposure:
  - Obtain a COVID-19 test on calendar day 5;
  - Conduct daily ~~**pre-screening**~~ **COVID-19 symptom screening** with temperature checks;
  - Wear a mask in the workplace for 10 calendar days after exposure, even if mask wearing is not otherwise required by DoD guidance;
  - Practice hand and cough hygiene;
  - Refrain from sharing headsets or other objects used near the face;
  - Continue to physically distance as much as possible; and
  - Clean and disinfect their workspace daily
- In all situations, for a full 10 days after last contact with a confirmed case, Service members must continue to self-monitor, and practice strict adherence to all non-pharmaceutical intervention mitigation strategies, and, if not fully vaccinated, wear masks, avoid crowds and practice physical distancing, hand and cough hygiene, maintain adequate indoor ventilation, and perform environmental cleaning and disinfection. In addition, Service members located outside the United States identified as close contacts must follow host-nation policies, as applicable.

Testing Quarantined Individuals Who Develop Symptoms:

Test eligible Service members in quarantine who develop symptoms commonly associated with COVID-19.

- If laboratory positive: The Service member becomes a case and must be isolated (see above).
- If laboratory negative: The Service member must continue to follow procedures for quarantine as outlined above.

Recommendations for Testing During the Period Following Initial Diagnosis of COVID-19:[22]

- For Service members previously diagnosed with COVID-19 who remain asymptomatic after recovery, polymerase chain reaction retesting is not recommended within 90 days from the date of initial diagnosis. Furthermore, in the event of subsequent close contact with confirmed COVID-19 positive individuals, additional quarantine (including any required post-travel quarantine) is not necessary or recommended for 90 days as long as the Service member remains symptom-free.
- If Service members become symptomatic during this time frame (whether or not they are a close contact of a case) they must self-isolate immediately and be evaluated by a health care provider to determine if they may have been re-infected with SARS-CoV-2 or if symptoms are caused by another etiology. Isolation may be warranted during this time, particularly if symptoms developed within 10 days after close contact with an individual who has contracted COVID-19.

Aircrew Notification: In situations where a Service member is identified as a case within 72 hours after medical transport in the en route care system, local public health authorities at the receiving MTF, or at the closest MTF if the case is transferred to a civilian medical facility, must notify the regional Theater Patient Movement Requirements Center to initiate contact tracing and air crew exposure procedures.

Contacts of Contacts: There is no indication to quarantine asymptomatic Service members who are contacts of contacts; they should continue to self-monitor for symptoms.

5.5. RESTRICTING WORKPLACE ACCESS – PERSONNEL OTHER THAN SERVICE MEMBERS.

a. Personnel other than Service members who have signs or symptoms consistent with COVID-19[23] will notify their supervisor and not come to the DoD workplace. Personnel who develop any signs or symptoms consistent with COVID-19 during the workday must immediately distance from other workers, put on a mask even if mask wearing is not otherwise required by DoD guidance, notify their supervisor, and promptly leave the DoD workplace.

b. Regardless of COVID-19 vaccination status, personnel who test positive for COVID-19 will remain out of the workplace for 5 days **(day 0 is the day symptoms started or date of specimen collection if asymptomatic).** Individuals may return to the DoD workplace after 5 days, if either: (1) they have no symptoms; or (2) if they are afebrile for more than 24 hours and any remaining symptoms are resolving. Mask wearing must continue in the workplace for an additional 5 days **(for a total of 10 days post-positive result)**, even if mask wearing otherwise is not required by DoD guidance.

[22] Beyond the 90-day recovery window, Service members revert to protocols for individuals who have never been diagnosed with COVID-19.
[23] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

c. Personnel with potential exposure to COVID-19 based on close contact with a person who has a laboratory confirmed, clinically diagnosed, or presumptive case of COVID-19 will notify their supervisor.

1. Asymptomatic personnel with potential exposure to COVID-19 based on close contact who are: (1) not fully vaccinated; **or** (2) are **not up-to-date with the COVID-19 vaccine** ~~**more than 5 months out from their second mRNA vaccine dose (i.e., Pfizer-BioNTech/Comirnaty or Moderna/Spikevax) and have not received a COVID-19 booster dose; or (3) more than 2 months out from their Johnson & Johnson/Janssen vaccine and have not received a COVID-19 booster dose**~~ will remain out of the workplace for 5 days. Regardless of vaccination status, asymptomatic personnel with potential exposure to COVID-19 based on close contact must wear a mask in the workplace for 10 days, even if mask wearing otherwise is not required by DoD guidance.

2. In cases of mission-essential activities that must be conducted on site, asymptomatic personnel with potential exposure to COVID-19 based on close contact, who otherwise would need to remain out of the workplace, may be granted an exception to continue to work on site provided they remain asymptomatic, do not have a positive test for COVID-19, and comply with the following key practices for 5 days after the last exposure:

- Obtain a COVID-19 test on day 5;
- Conduct daily pre-screening with temperature checks;
- Wear a mask in the workplace for 10 days after exposure, even if mask wearing is not otherwise required by DoD guidance,
- Practice hand and cough hygiene;
- Refrain from sharing headsets or other objects used near the face;
- Continue to physically distance as much as possible; and
- Clean and disinfect their workspaces daily.

This exception may be granted by the first general/flag officer or member of the SES, or equivalent, in the chain of command/chain of supervision or, for those locations that do not have general/flag officers or SES leaders, by O-6 installation commanders. If the individual develops signs or symptoms consistent with COVID-19 during the duty period, he/she will be sent home immediately.

3. Personnel performing duties outside the United States will also follow applicable geographic Combatant Commander guidance to address HN policies.

5.6. RESTRICTING WORKPLACE ACCESS – STATE AND LOCAL RESTRICTIONS.

In States and localities that require members of the general public to stay at home, DoD Service members and civilian employees may report to work as directed to do so by a commander or supervisor.

5.7. ISSUANCE OF MEDICAL PERSONAL PROTECTIVE EQUIPMENT.

Medical personal protective equipment (PPE) items, such as N95 respirators, are reserved for use in high-risk procedures and for use by those at increased risk of severe disease, and should not be issued outside of these circumstances unless local commanders or supervisors determine they are necessary to respect HN or local jurisdiction guidelines. In those instances, commanders or supervisors, in consultation with public health specialists and legal counsel, and with consideration of national or local jurisdictional agreements, such as Status of Forces Agreements, will determine if medical PPE items will be issued to non-medical personnel to respect such guidelines. The PPE supply must be optimized and the below guidelines should be followed, in addition to consulting CDC-published strategies found at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html.

Although it is likely that expired respirators will be scarce 2 years into the pandemic, stockpiles of new respirators may eventually pass their expiration date. N95 respirators in the pandemic stockpiles that have exceeded their manufacturer's recommended shelf-life and expiration date should not be discarded. Current CDC guidance addresses this issue describing strategies for optimizing the supply of N95 respirators in health care settings where there is a limited supply.[24] Use of expired respirators may be prioritized for situations where personnel are not exposed to the virus that causes COVID-19, such as for training and fit testing. The manufacturer should be contacted for additional guidance on the use of expired respirators for any other reasons. Those responsible for ordering respirators should not do so with the idea that expired devices can be readily re-used; rather, expired devices should be discarded as per National Institute for Occupational Safety and Health pre-pandemic policy.

5.8. CLEANING AND DISINFECTING.

The CDC and OSHA have established enhanced cleaning and disinfection guidance for the cleaning and disinfection of work areas, including those areas previously occupied by workers with known or suspected COVID-19. Enhanced cleaning and disinfection should also be performed for common use, high-touch, high-density spaces and equipment such as in lobbies, restrooms, break areas, office elevators, and stairwells. It should also include tools and equipment that are shared by multiple users.

Personnel who are cleaning workspaces or conducting maintenance activities in areas previously occupied by someone who is known or suspected to have contracted COVID-19 should wear gloves, face shields (if there is a risk of splash), disposable gowns or aprons, and other protection as recommended on the Safety Data Sheet or EPA label of the cleaning or disinfectant product. When using electrostatic sprayers for disinfection, personnel should wear PPE as specified in the EPA product label. Personnel should follow all personal hygiene requirements (e.g., handwashing, equipment doffing) after completion of work activities as recommended by CDC guidance at: https://www.cdc.gov/coronavirus/2019-ncov/community/disinfecting-building-facility.html and https://www .cdc.gov/niosh/docs/2012-126/pdfs/2012-126.pdf. Segregation of such work areas prior to cleaning and disinfection is

[24] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/index.html.

necessary. When the cleaning and disinfection procedures described above are complete, demarcation of areas where the individuals known or suspected to have contracted COVID-19 previously worked is not necessary.

5.9. HEATING, VENTILATION, AND AIR CONDITIONING (HVAC).

The SARS-CoV-2 virus is transmitted mainly by large respiratory droplets, but infected individuals generate aerosols and droplets across a large range of sizes and concentrations. There is no need to shut down air HVAC, air handling systems, or air vents to prevent the spread of COVID-19 within a building. Increasing indoor air movement and ventilation is a cornerstone of COVID-19 transmission mitigation strategy. Ensure existing HVAC systems in buildings are functioning properly, ensure the amount of outside air supplied to the HVAC system is maximized to the extent appropriate and compatible with the HVAC systems' capabilities, and ensure the use of air filters that have a Minimum Efficiency Reporting Value-13 or higher filter where the system can accommodate this type of filtration efficiency. In addition to the requirements for existing HVAC systems, building managers should consider other measures to improve ventilation in accordance with CDC guidance (e.g., opening windows and doors to let in outside air) at: https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html.

5.10. OSHA-REQUIRED ILLNESS RECORDKEEPING.

COVID-19 is a recordable occupational illness if a worker contracts the virus as a result of performing his or her occupational duties and if all of the following conditions are met: (1) COVID-19 illness is a confirmed case; (2) contraction of COVID-19 is work-related as described in 29 CFR § 1904.5 (this condition will require a determination by the commander or supervisor who may require input from the worker's health care provider); (3) the case of illness satisfies the requirement as a recordable illness as set forth in 29 CFR § 1904.7 (e.g., medical treatment beyond first aid is required, the number of calendar days away from work meets the stated threshold).[25]

5.11. SAFETY AUDITS, INSPECTIONS, AND TRAINING.

To ensure maximum compliance with physical distancing guidance and telework arrangements, routine industrial hygiene and safety surveys required by DoDI 6055.05, "Occupational and Environmental Health," and DoDI 6055.01, "DoD Safety and Occupational Health (SOH) Program," may be discontinued at the discretion of the Component's Designated Agency Safety and Health Official, for the duration of the pandemic or the workplace returns to HPCON 0, whichever comes sooner.

The annual survey requirements specified in paragraph 3.8 of DoDI 6055.12, "Hearing Conservation Program (HCP)," may be suspended by DoD Components at the discretion of the Component's Designated Agency Safety and Health Official during the COVID-19 pandemic so

[25] The reporting requirements are described in more detail in DoDI 6055.07, "Mishap Notification, Investigation, Reporting, and Record Keeping," and at: https://www.osha.gov/recordkeeping.

long as there is a good faith effort to complete required services and compliance is not otherwise possible. These requirements should resume upon the conclusion of the pandemic or the workplace returns to HPCON 0, whichever comes sooner.

Spirometry can be safely performed by following the CDC guidance for increased ventilation and regular room cleaning and disinfection, patient screening, and implementation of single use disposable items. The guidance for pulmonary function tests is contained in the Defense Health Agency Deputy Assistant Director for Medical Affairs Memorandum, "Outpatient Pulmonary Function Tests (PFT) During COVID-19 Pandemic," August 18, 2020, and interim technical guidance for the safe performance of spirometry is available from the American College of Occupational and Environmental Medicine.[26]

5.12. MAINTENANCE.

If workers are planning to conduct maintenance in a residence where a person who is known or suspected to have contracted COVID-19 resides and the maintenance is necessary and cannot be delayed, the resident should be asked to remove all items that would impede the work of the maintenance personnel. The resident should clean the area of any dirt, debris, dust, etc. that would impact the effectiveness of surface disinfectant used by maintenance personnel. Workers should maintain a distance of at least 6 feet from the resident who is known to have or suspected of having contracted COVID-19, and ask that the resident remain in a separate room while maintenance is conducted. If a separate room for the resident is unavailable and the worker is unable to remain 6 feet in distance from the resident during the work, appropriate protective equipment for close contact must be worn by the worker. If necessary, clean and disinfect the work area following the procedures for personnel protection described in section 5.8.

[26] September 1, 2021. https://acoem.org/Guidance-and-Position-Statements/Guidance-and-Position-Statements/Occupational-Spirometry-and-Fit-Testing-in-the-COVID-19-Era-2021-Interim-Recommendations-from-the-A.

SECTION 6: MEETINGS

For any planned in-person meetings, events, and conferences (referred collectively herein as "meetings") sponsored by DoD with more than 50 participants in a county or equivalent jurisdiction where the CDC COVID-19 Community Level is high, the meeting organizer will obtain advance written approval from the DoD or Office of the Secretary of Defense (OSD) Component head concerned to hold the meeting. The DoD or OSD Component head concerned may delegate this authority in writing to their Principal Deputy (or equivalent) but no lower. **For the Pentagon Reservation, the approval authority is the DA&M and this authority may not be further delegated.**

For any in-person meetings in a county or equivalent jurisdiction where the CDC COVID-19 Community Level is high or medium, the meeting organizer will require all attendees, including Service members and DoD civilian employees, to show a completed DD Form 3150, "Contractor Personnel and Visitor Certification of Vaccination" **and will follow the applicable requirements in section 5.2 for physical distancing. For any in-person meetings in a county or equivalent jurisdiction where the CDC COVID-19 Community level is low, the meeting organizers will follow the applicable requirements in section 5.2 for physical distancing.**

In-person attendees who are not fully vaccinated, or who decline to provide information about their vaccination status, may not attend the meeting if they do not show the meeting organizer proof of a negative FDA approved or authorized COVID-19 test completed no earlier than 72 hours prior to the meeting, and at least weekly if the meeting is greater than one week in duration. Meetings do not include military training and exercise events conducted by MILDEPs.

SECTION 7: TRAVEL

This section covers official and unofficial travel and provides current pre- and post-travel guidance for Service members, DoD family members, DoD civilian employees, and DoD contractor personnel.

Heads of DoD and OSD Components may implement more restrictive guidance and additional FHP measures based on mission requirements and local risk assessments, in consultation with their medical staffs and public health authorities.

The Secretaries of the MILDEPs, heads of OSD Components, Commanders of the GCCs, and the Commander, U.S. Transportation Command **(USTRANSCOM)**, may choose to exempt assigned aircrew and aircraft maintenance recovery team members on commercial, military contracted, and organic military aircraft from this section, to the extent permissible, consistent with applicable legal requirements. In addition, patients and their attendants in the en-route care system are exempt from restriction of movement (ROM) requirements and may be exempted from testing requirements by the Theater Validating Flight Surgeon until they arrive at their final treatment destination. Medical care will not be delayed due to ROM requirements.

The Commander, USTRANSCOM, may further waive the requirements of this section in order to continue execution of the Joint Deployment and Distribution Enterprise as required to project and sustain the joint force globally. This includes forces (aircrews, vessel crews, and mission essential personnel) ordered on prepare-to-deploy orders alert status, air refueling, global patient movement, mortuary affairs support, inland surface, sea, and air sustainment missions, support to other federal departments and agencies (as approved by the Secretary of Defense); and moves of personnel and equipment that support USTRANSCOM's global posture requirements.

7.1. GENERAL TRAVEL GUIDANCE.

Fully vaccinated individuals are not restricted from official travel, both domestic and international. Individuals who are not fully vaccinated, or who decline to provide information about their vaccination status, are limited to mission-critical official travel, both domestic and international. "Mission-critical" will be determined by the traveler's DoD or OSD Component head, who may delegate this authority in writing to the Component's Principal Deputy (or equivalent) but no lower. **For the purpose of this FHP guidance, travel associated with permanent changes of station, travel** in connection with Authorized or Ordered Departures issued by the Department of State**, or travel in evacuations ordered by the appropriate DoD official** is deemed to be "mission-critical."

During all official travel, travelers will follow all applicable Federal, State, local, and commercial air carrier requirements, and applicable HN requirements as a means to respect HN law. In addition to completion of required or recommended ROM, additional requirements may be necessary when traveling to, or from, locations outside, and within, the United States, travelers will follow any requirements in the Electronic Foreign Clearance Guide pertaining to entry, movement, or operations into a HN. Travelers will also refer and adhere to local updates

in HN for travel and movement within the HN.

For travel via military airlift (contracted or organic), Aerial Point of Embarkation (APOE) health screening is mandatory. Travelers who have a medical issue identified during screening or who refuse to be screened at the APOE may be denied travel.

The waiver authority available to the Secretaries of the MILDEPs, heads of OSD Components, Chief of the National Guard Bureau, and Commanders of the GCCs for official travel is specified in section 7.4. Travel that is limited to transit between, and through, foreign countries contained wholly within a single GCC area of responsibility, and between GCC areas of responsibility, is not subject to this memorandum and will be managed by each relevant GCC or GCCs as appropriate.

7.2. RISK ASSESSMENT PRIOR TO TRAVEL.

It is important for the appropriate commander or supervisor, assisted by medical personnel, to complete a risk assessment for each traveler before travel, as set forth below, including an assessment of the health status and itinerary. Specifically:

- For Service members, a risk assessment is required before all travel.
- For DoD family members, reimbursement for official travel may only occur after the Service members certifies, to the best of his or her knowledge, that family members have completed a risk assessment. DoD family members are strongly encouraged to complete a risk assessment before unofficial travel as well.
- For DoD civilian employees, a risk assessment is required before official travel. DoD civilian employees are strongly encouraged to complete a risk assessment before unofficial travel as well.
- ~~**For DoD contractor personnel, DoD contracting officers will ensure that all contracts that include performance requiring official travel outside the United States require DoD contractor personnel to complete a risk assessment. DoD contractor personnel are strongly encouraged to complete a risk assessment before unofficial travel as well.**~~

The risk assessment of the health status of the traveler will include, at a minimum, determining:

- Whether the individual is familiar with how to self-monitor, and what actions to take, if he or she develops signs or symptoms consistent with COVID-19 or contracts COVID-19;
- Whether the individual has exhibited any signs or symptoms consistent with COVID-19 within the previous 10 days;
- Whether the individual has had close contact with anyone having, or known to have exhibited, signs or symptoms consistent with COVID-19, or who has tested positive for COVID-19 within the previous 10 days;
- Whether the individual has recently recovered from COVID-19 and, if so, when and if they have documentation of a positive viral test and documentation of recovery

from a health care provider;
- Whether the individual is fully vaccinated or up-to-date with COVID-19 vaccines and, if so, when, and whether they have proof of vaccination (CDC vaccination card or other medical documentation);
- Whether the individual has traveled to a country, State, territory, county, or city with high or increasing risk of COVID-19 as defined by the CDC in Travel Health Notices;
- Whether the individual is at increased risk of severe illness of COVID-19 as defined by the CDC. Additional details can be found at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html. For DoD civilian personnel, disclosure of this information is voluntary; and
- The status of community spread of COVID-19 for the travel destination.

DoD Components may consider requiring contractors with contracts calling for official travel outside the United States to direct their employees to perform a risk assessment prior to such travel. When required, the contractor may tailor the assessment elements according to company policy and should document the risk assessment. At a minimum, when required, the risk assessment should include a self-health assessment performed by the traveler, and a review of the travel itinerary by the traveler's supervisor. The contractor should not be required to disclose the results of the assessment with the DoD. DoD contractor personnel are encouraged to complete a risk assessment before unofficial travel as well.

In all cases, no personnel may engage in official travel if they have tested positive for COVID-19 and have not yet met the criteria for discontinuing isolation, they are symptomatic, or they are pending COVID-19 test results. After discontinuing isolation, personnel should avoid official travel until 10 calendar days after their symptoms started or the date of their positive test. If these personnel must travel on days 6 through 10, they must properly wear a well-fitting mask when they are around others for the entire duration of travel, even if mask wearing is not otherwise required by DoD guidance. Official travel should also be delayed if, in the past 10 days, an individual has been in close contact with someone who has tested positive for, and/or been symptomatic of, COVID-19 and requires self-quarantine. Prior to travel, all official travelers should be educated on how to self-monitor and what actions to take if one develops signs or symptoms consistent with COVID-19 or contracts COVID-19.

7.3. ROM REQUIREMENTS.

a. Steps to Be Taken During ROM. During any required or recommended ROM period, individuals will, to the fullest extent practicable:

- Restrict movement to their residence or other appropriate domicile[27] as much as possible.
- Maintain a distance of greater than 6 feet from anyone who did not, or will not, travel

[27] The ROM location for Dynamic Force Employment organizations and individuals will be identified through a case-by-case determination coordinated with the force provider and GCC.

with them, including family members or roommates; wear masks at all times around individuals; and employ hand washing practices in accordance with CDC guidance; avoid crowds; avoid the use of public transportation; and avoid close interaction with pets or other animals for 10 days after travel even if the ROM period is shorter than 10 days.

- Consider their ROM location as their authorized duty location.
- Self-monitor for subjective fever (that is, feeling feverish) or actual fever (≥100.4°F or ≥38°C) by taking their temperature twice a day, and self-monitor for cough, difficulty breathing, or other COVID-19 signs and symptoms as described by the CDC at: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. If signs or symptoms consistent with COVID-19 develop during the 14-day self-monitoring period, individuals will, to the fullest extent practicable, immediately self-isolate, limit close contact with others, and, if appropriate, seek advice by telephone or other authorized communication modalities from an appropriate healthcare provider to determine whether medical evaluation and testing for COVID-19 is needed.
- For Service members, notify their chain of command if they, or persons in their household, develop signs or symptoms consistent with COVID-19. Such health information will be used only for FHP purposes and will be protected in accordance with applicable laws and policy.
- DoD civilian employees should notify supervisors if they develop, or have had contact with anyone who exhibits, signs or symptoms consistent with COVID-19. Such health information will be used only for FHP purposes and will be protected in accordance with applicable laws and policy.
- Telework when practicable per direction of their commander or supervisor.
- For personnel whose presence is required in the workplace by their supervisor, consider whether and when to return to work during the ROM period in accordance with section 5.

b. Additional ROM Guidance:

- If ROM is conducted prior to travel, travel to and from an APOE following ROM completion will, to the maximum extent possible, be conducted in a manner that minimizes the risk of personnel being exposed to, or contracting, the virus that causes COVID-19 during travel.
- For MILDEP ships and submarines, underway time from port of embarkation/debarkation to port of debarkation/embarkation may be used to meet ROM requirements provided no cases have occurred while underway and there has been no contact with personnel from other vessels (e.g., resupply vessels) that would permit transmission.

c. Exceptions to ROM:

- Pre- and post-travel ROM is not required for individuals who have fully recovered from a laboratory-confirmed diagnosis of COVID-19 within the previous 90 days prior to travel, or for individuals who are fully vaccinated. Those fully recovered and

fully vaccinated will self-monitor for COVID-19 symptoms after travel. However, Service members will isolate and get tested for COVID-19 if they develop signs or symptoms consistent with COVID-19.

- ROM after arrival at the travel destination may or may not be required by the HN if travelers have undergone COVID-19 screening testing prior to travel. If the relevant GCC requires a ROM upon arrival in the country as a means of respecting HN law, then a pre-deployment ROM is not required. Travelers should consult the Electronic Foreign Clearance Guide (https://www.fcg.pentagon.mil/fcg.cfm) and check with the MILDEPs and GCCs for current information.

7.4. TESTING REQUIREMENTS.

a. Pre-travel, post-travel, and ROM-associated COVID-19 screening testing is authorized for official domestic and international air travel at military medical treatment facilities on a non-reimbursable basis for Service members, DoD civilian employees, DoD contractor employees who are traveling for official DoD business, members of the Selected Reserve (including members of the National Guard), and family members approved to accompany DoD personnel. Testing is authorized for official travel on presentation of an electronic or paper copy of orders at military medical treatment facilities. **The cost of testing recommended or required for official travel, and not available through a MTF or not covered (or reimbursable) through travel insurance, can be claimed in a travel voucher as a miscellaneous expense under agency travel policies.**

b. The testing guidance indicated below is recommended for personnel-conducting official international air travel. It is recommended that personnel maintain proof of the negative test during travel. If the destination location requires a specific test or stricter test timing, personnel must follow the destination location requirement instead, which may be reflected in the Electronic Foreign Clearance Guide.

- Pre-travel viral[28] testing is recommended 1 to 3 days prior to departure of the commercial or military airlift for both travel from the United States to a foreign country or from a foreign country to the United States.
- Post-international travel viral testing 3 to 5 days after the completion of travel is recommended for active duty Service members and DoD civilian employees.

c. The testing guidance indicated below is recommended for active duty Service members conducting unofficial international air travel. It is recommended that the individuals maintain proof of the negative test during travel. Active duty Service members are authorized to receive pre-international and post-international travel testing.

- Pre-travel viral testing is recommended 1 to 3 days before departure of the commercial or military airlift for travel from the United States to a foreign country.

[28] Testing in this guidance refers to tests that utilize molecular or, in certain limited circumstances, antigen testing methods, in accordance with the DoD Coronavirus Task Force Diagnostics and Testing Lead Memorandum, "Optimization of Coronavirus Disease 2019 (COVID-19) Testing Resources," March 8, 2021.

Travelers will adhere to the destination testing requirements.

- Pre-travel viral testing is recommended 1 day before departure of the commercial or military airlift for travel from a foreign country to the United States.
- Post-international travel viral testing 3 to 5 days after the completion of travel is recommended for active duty Service members and DoD civilian employees.

7.5. SPECIFIC GUIDANCE BY TYPE OF TRAVEL.

7.5.1 Travel from the United States to a Foreign Country

a) Official Travel

i) Service members

- Will conduct a travel-associated ROM as follows unless a ROM exception described above applies:
  - Upon arrival at the foreign country destination:
    - As a means to respect HN regulations, Service members will observe applicable HN public health measures.
    - ROM will be conducted as follows:
      - At least 10 days without testing; or, after an appropriate risk assessment, the head of an OSD Component or Secretary of a MILDEP may, consistent with applicable HN public health measures, decrease to a ROM for 5 days with a negative viral test at the end of the 5-day ROM.
      - MILDEPs maintain the authority to determine how necessary ROM and movement, including the mode of transportation to final destinations, are executed.
  - If it is necessary as a means to respect HN regulations to undertake a pre-arrival ROM to observe applicable HN public health measures, the Service member will follow the 10-day or 5-day ROM procedures described above at an appropriate domicile prior to departure and complete pre-travel testing within one to three days prior to departure.
  - Only one ROM is required, either before travel or after arrival.
  - Must follow all other requirements imposed by the GCC with responsibility over the destination geographic area, including all applicable HN procedures as a means to respect HN law, and all requirements of the Electronic Foreign Clearance Guide.

ii) DoD family members

- Service members must attest that, to the best of their knowledge, their family members have followed the same requirements as those set forth for Service members in this guidance. Failure to do so may result in delay or cancellation of previously authorized travel. This attestation requirement will be incorporated into travel orders issued to Service members.

iii) DoD civilian employees

- Will conduct a travel-associated ROM and other FHP practices as described above for Service members.

iv) DoD contractor personnel

- DoD contracting officers will ensure that all contracts that include performance outside the United States require DoD contractor personnel to comply with the country entry requirements of the respective GCC (which may include screening, ROM, and testing), as reflected in the Electronic Foreign Clearance Guide, and all applicable HN procedures necessary to respect HN law. The GCC may waive such additional requirements, consistent with existing authorities.

b) Unofficial Travel
   i) Service members will comply with their respective MILDEP guidance, DoD Component-specific guidance, and/or GCC and applicable HN procedures, as necessary to respect HN law, for the areas to which, and through which, they are traveling.
   ii) DoD family members, DoD civilian employees, and DoD contractor personnel must comply with the guidance and/or applicable HN procedures, as necessary to respect HN law, for the areas to which, and through which, they are traveling, and are strongly recommended to follow the FHP guidance for Service members provided within this document and any other DoD Component-specific guidance.

7.5.2. Travel From or Through a Foreign Country to the United States

a) Official Travel
   i) Service members
      - It is recommended that Service members conduct testing as described above, prior to departure. Service members will conduct a risk assessment as described in "Determining Whether to Travel," above. If COVID-19 infection is indicated by the risk assessment or testing, delay travel and consult a health care provider for clearance to travel.
      - Service members will conduct a risk assessment as described in "Determining Whether to Travel" above upon arrival in the United States. Those who become ill, or have had close contact with a person known to have contracted COVID-19, during travel will follow the requirements in section 5 related to workplace access.
      - ROM will be conducted as follows: Unless a ROM exception described above applies, if traveling from or having traveled through a foreign country, the Service member will, upon arrival at his or her destination domicile:
        - ROM for at least 10 days without testing.
          - After an appropriate risk assessment, the head of the OSD Component or Secretary of the MILDEP concerned may decrease to a ROM for 5 days with a negative viral test at the end of the 5-day ROM.
          - Personnel whose presence is required in the workplace by their supervisor may return to work during the ROM period in accordance with section 5.
        - For any travel-associated ROM, follow the procedures specified above in the "Steps to Be Taken During ROM" section. The ROM requirements may be reduced or waived by the appropriate head of an OSD Component or Secretary of a MILDEP on a case-by-case basis with appropriate risk assessment and mitigation measures.
        - Comply with all installation, State, and local government guidance.
        - Are recommended to get tested for COVID-19 between 3 and 5 days after

arrival, regardless of their vaccination status.

ii) It is recommended that DoD family members conduct pre-travel screening and testing as described above and are strongly recommended to follow the FHP guidance that is provided within this document for Service members during all travel.

iii) It is recommended that DoD civilian employees and DoD contractor personnel conduct pre-travel screening and testing as described above and are strongly recommended to follow the FHP guidance for Service members that is provided in this document during all travel. Any applicable requirements in section 5 must be met prior to returning to a DoD workplace.

b) Unofficial Travel

i) Service members

- It is recommended that Service members conduct pre-travel testing as described above. Service members will follow risk assessment and ROM procedures described above in the Official Travel section.
- Service members will comply with DoD Component-specific guidance and/or procedures of the GCC, including those necessary to respect HN procedures applicable to the countries to which, and through which, they are traveling.
- Service members will conduct a risk assessment as described in "Determining Whether to Travel" above upon arrival in the United States. Those who become ill, or have had close contact with a person known to have contracted COVID-19 during travel, must self-isolate (if ill) or quarantine (if exposed but not ill) and notify their chain of command or supervisor. Exception: Individuals fully recovered from a laboratory-confirmed diagnosis of COVID-19 infection within the previous 3 months or those who are fully vaccinated are not required to quarantine as long as they remain symptom-free.

ii) DoD family members may follow the FHP guidance, including pre-travel screening, for Service members provided within this document.

iii) DoD civilian employees and DoD contractor personnel may follow the FHP guidance, including pre-travel screening for Service members provided within this document. Any applicable requirements in section 5 must be met prior to returning to a DoD workplace.

7.5.3. Travel Within the United States

a) Official Travel

i) Service members

- Will comply with military installation, State, and local government travel restrictions.
- Will comply with their DoD Component-specific guidance and/or procedures for screening, ROM, and testing, and should review and consider CDC guidance.

ii) DoD family members are strongly recommended to follow the FHP guidance for Service members provided within this document during all travel.

iii) DoD civilian employees and DoD contractor personnel will conduct pre-travel screening as described above and are strongly recommended to follow the guidance for Service members provided within this document for Service members during all travel. Any applicable requirements in section 5 must be met prior to returning to a DoD workplace.

b) Unofficial Travel
   i) Service members
      - ~~**Should consult the COVID-19 Travel Restrictions Installation Status Update available at https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/ prior to travel.**~~
      - Will comply with military installation, State, and local government travel restrictions.
      - Will comply with their DoD Component-specific guidance and/or procedures for screening, ROM, and testing.
   ii) DoD family members are strongly recommended to follow the FHP guidance for Service members provided within this document during all travel.
   iii) DoD civilian employees and DoD contractor personnel are strongly recommended to follow the guidance for Service members provided above. Any applicable requirements in section 5 must be met prior to returning to a DoD workplace.

7.6. ADDITIONAL GUIDANCE FOR RESERVE AND NATIONAL GUARD PERSONNEL.

1. The Secretaries of the MILDEPs may issue any additional procedural guidance as necessary for Reserve Component personnel.

2. Reserve Component (including National Guard) personnel on official travel will complete any required health and ROM measures, including home-based quarantine or self-isolation if required, prior to the end of the official duty period.

3. Reserve Component (including National Guard) personnel on official travel who are not eligible for treatment at a military medical treatment facility, or who are not within the established access radius around a military medical treatment facility, may obtain COVID-19 official travel related testing at a civilian testing site and submit for reimbursement on their travel voucher.

4. For National Guard (NG) members supporting Federal Emergency Management Agency mission assignments or for other activities undertaken by NG personnel in a title 10 or title 32 duty status, the Chief of the National Guard Bureau, in coordination with the Secretaries of the Army and the Air Force, may issue redeployment guidance to the States, territories, and the District of Columbia to support mission requirements, while minimizing risks to NG members and local communities. Reserve Component personnel in support of another department or agency will complete any required health and ROM measures, including home-based quarantine or self-monitoring, prior to the end of the period of support to that other department or agency.

7.7. ADDITIONAL GUIDANCE TO ASSIST COMMANDERS WITH TRAVEL DECISIONS.

1. The Department of Defense Joint Travel Regulations are available at: https://www.defensetravel.dod.mil/site/travelreg.cfm

2. The DoD COVID-19 Response and Operations Platform, available at https://covid-status.data.mil/#/, provides travel scenarios and COVID-19 installation status and information to scope, plan, and approve travel by providing awareness of Health Protection Condition levels and COVID-19 hotspots.

3. The Defense Health Agency's Armed Forces Health Surveillance Division provides a "Trajectory of Civilian COVID-19 Cases by County" for the U.S. at the AFHSB COVID-19 Dashboard, available at:
   - https://go.intelink.gov/25BWvsS
   - https://covid-status.data.mil/#/

~~**4. Travel Restriction Installation Status Updates, available at: https://www.defense.gov/Explore/Spotlight/Coronavirus/**~~

4. COVID-19 Signs and Symptoms are available at: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

SECTION 8: PROTECTION OF PERSONALLY IDENTIFIABLE INFORMATION RELATED TO COVID-19

8.1. GENERAL.

Under this Force Health Protection Guidance, the DoD may collect and maintain sensitive and private information about individuals, including medical information. All personally identifiable information (PII) on individuals must be appropriately safeguarded. In implementing this guidance, DoD Components may collect, use, maintain, and/or disseminate only the minimum amount of PII necessary to prevent the spread of COVID-19 and to protect personnel in DoD workplaces. All personally identifiable information (PII) on individuals must be appropriately safeguarded under the Privacy Act of 1974 and DoDI 5400.11, "DoD Privacy and Civil Liberties Programs."

Due to the public health emergency, DoD Components are authorized to collect COVID-19 information from individuals whose place of duty is in the DoD workplace, to the extent such collection is necessary to implement the guidance above on workplace access and restriction. DoD Components are authorized to use DD Form 3112, "Personnel Accountability and Assessment Notification for Coronavirus Disease 2019 (COVID-19) Exposure," to collect this information (e.g., affected individual information, type of confirmed or possible health or safety issue). This form is located at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd3112.pdf.

Currently, the requirement for all Federal civilian employees to be vaccinated is not in effect. A U.S. district court judge issued a nationwide preliminary injunction prohibiting implementation and enforcement of civilian employee vaccination requirements based on EO 14043. Requirements subject to the injunction and not currently in effect are included in this guidance in a strikeout form for ease of reinstitution by USD(P&R) should the injunction be lifted.

8.2. ADDITIONAL REQUIREMENTS FOR INFORMATION COLLECTED FROM DOD CIVILIAN EMPLOYEES.

Medical information obtained from DoD civilian employees, including vaccination status, will be accessible only to immediate supervisors, authorized human resources officials, ~~and, for exemption requests, Decision Authorities and subject matter experts,~~ who must access the information to implement the guidance in this memorandum. The Rehabilitation Act's requirements on confidentiality of medical information apply whether or not a DoD civilian employee has a disability.

DoD personnel will use appropriate safeguards in handling and storing DoD civilian employee medical information, including a DoD civilian employee's proof of vaccination; any medical information on the DD Forms 3175, 3176, and 3177, and COVID-19 test results. Appropriate safeguards may include encrypting emails and electronic files, and role-based access

to electronic storage environments where this information is maintained. In the event the information is maintained in paper form, supervisors and other authorized DoD personnel must ensure DoD civilian employee medical information remains confidential and is maintained separately from other personnel files (e.g., stored in a separate, sealed envelope marked as confidential DoD civilian employee medical information and maintained in locked file cabinets or a secured room). DoD Components are advised to refer to applicable internal guidance on the handling, storage, and disposition of DoD civilian employee medical records, and to consult their Component Privacy Officer as needed for further guidance.

~~Consistent with the Religious Freedom Restoration Act of 1993, 42 U.S.C. chapter 21B, and Title VII of the Civil Rights Act, 42 U.S.C. chapter 21, subchapter VI, individuals seeking a religious exemption from the vaccination requirement will submit to DoD supporting information about their religious beliefs and practices in order for DoD to evaluate the exemption request. Information collected from individuals under this guidance supporting vaccine exemption requests will be treated in accordance with applicable laws and policies on privacy, including the Privacy Act of 1974 and DoDI 5400.11, "DoD Privacy and Civil Liberties Programs," the Rehabilitation Act of 1973, as amended ("Rehabilitation Act"), and 5 CFR part 293, subpart E. While such information may be sensitive and is to be safeguarded, it is not covered by the Health Insurance Portability and Accountability Act (HIPAA) and the associated HIPAA Rules.~~

~~Information gathered under this guidance collected from DoD civilian employees related to exemption requests may be shared with immediate supervisors, authorized human resources officials, Decision Authorities, and, in appropriate cases, subject matter experts, who must access the information to implement the exemption process. DoD Components are advised to consult their Component Privacy Officer and servicing legal office if there is a need to share medical or religious information collected under this guidance with DoD personnel beyond what this guidance permits or with individuals outside of DoD. Religious information will be accessible only to those persons who have a role in carrying out the exemption procedures outlined in section 2 of this memorandum.~~

SECTION 9: DEFINITIONS

Close contact. Close contact is defined as someone who was within 6 feet of a person who has contracted COVID-19 for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated and irrespective of whether the person with COVID-19 or the contact of such a person was wearing a face covering or mask or respiratory personal protective equipment.

Family member. See the definition in 5 CFR § 630.201.

Fully vaccinated.

An individual is considered "fully vaccinated" when at least 2 weeks have elapsed after a second dose of a two-dose COVID-19 vaccine series (e.g., PfizerBioNTech/Comirnaty, or Moderna/Spikevax vaccines), or 2 weeks after receiving a single dose of a one-dose COVID-19 vaccine (e.g., Johnson & Johnson's Janssen vaccine) that are: (1) fully licensed or authorized or approved by the FDA; (2) listed for emergency use on the World Health Organization Emergency Use Listing (e.g., AstraZeneca/Oxford); or (3) approved for use in a clinical vaccine trial for which vaccine efficacy has been independently confirmed (e.g., Novavax).

An individual is "not fully vaccinated" if the individual either has not completed the full COVID-19 vaccination dose series; or declines to provide his or her COVID-19 vaccination status and declines to provide any requested proof of that status.

Those with previous COVID-19 infection(s) or previous serology are not considered fully vaccinated on that basis for the purpose of this guidance.

HPCON level. A framework to inform an installation's population of specific health protection actions recommended in response to an identified health threat, stratified by the scope and severity of the health threat.

Mask. Acceptable masks are non-medical disposable masks; masks made with breathable fabric (such as cotton); masks made with tightly woven fabric that does not let light pass through when held up to a light source; masks with two or three layers; masks with inner filter pockets, or, on a voluntary basis in non-medical settings, an N95-type filtering face piece. A good practice is to wear a disposable mask underneath a cloth mask for added protection as long as this does not interfere with breathing. Novelty or non-protective masks, masks with ventilation valves, bandanas, and face shields are not authorized as a substitute for masks. Masks must fit snugly around the nose and chin with no large gaps around the sides of the face.

United States. The 50 States, U.S. commonwealths, U.S. territories, and the District of Columbia.

Up-to-Date. A person has received all recommended COVID-19 vaccines, including any booster dose(s) **recommended** when eligible.

The Wayback Machine - https://web.archive.org/web/20220811215720/https://www.cdc.gov/media/releases/2022/p0811-covid-...

Centers for Disease Control and Prevention

CDC streamlines COVID-19 guidance to help the public better protect themselves and understand their risk

Press Release

Embargoed Until: Thursday, August 11, 2022, 3:00 PM ET

Contact: Media Relations
(404) 639-3286

Today, CDC is streamlining its COVID-19 guidance to help people better understand their risk, how to protect themselves and others, what actions to take if exposed to COVID-19, and what actions to take if they are sick or test positive for the virus. COVID-19 continues to circulate globally, however, with so many tools available to us for reducing COVID-19 severity, there is significantly less risk of severe illness, hospitalization and death compared to earlier in the pandemic.

“We’re in a stronger place today as a nation, with more tools—like vaccination, boosters, and treatments—to protect ourselves, and our communities, from severe illness from COVID-19,” said Greta Massetti, PhD, MPH, MMWR author. “We also have a better understanding of how to protect people from being exposed to the virus, like wearing high-quality masks, testing, and improved ventilation. This guidance acknowledges that the pandemic is not over, but also helps us move to a point where COVID-19 no longer severely disrupts our daily lives.”

In support of this update CDC is:

- Continuing to promote the importance of being up to date with vaccination to protect people against serious illness, hospitalization, and death. Protection provided by the current vaccine against symptomatic infection and transmission is less than that against severe disease and diminishes over time, especially against the currently circulating variants. For this reason, it is important to stay up to date, especially as new vaccines become available.
- Updating its guidance for people who are not up to date on COVID-19 vaccines on what to do if exposed to someone with COVID-19. This is consistent with the existing guidance for people who are up to date on COVID-19 vaccines.
- Recommending that instead of quarantining if you were exposed to COVID-19, you wear a high-quality mask for 10 days and get tested on day 5.
- Reiterating that regardless of vaccination status, you should isolate from others when you have COVID-19.
    - You should also isolate if you are sick and suspect that you have COVID-19 but do not yet have test results.
        - If your results are positive, follow CDC’s full isolation recommendations.
        - If your results are negative, you can end your isolation.
- Recommending that if you test positive for COVID-19, you stay home for at least 5 days and isolate from others in your home. You are likely most infectious during these first 5 days. Wear a high-quality mask when you must be around others at home and in public.
    - If after 5 days you are fever-free for 24 hours without the use of medication, and your symptoms are improving, or you never had symptoms, you may end isolation after day 5.
    - Regardless of when you end isolation, avoid being around people who are more likely to get very sick from COVID-19 until at least day 11.
    - You should wear a high-quality mask through day 10.
- Recommending that if you had moderate illness (if you experienced shortness of breath or had difficulty breathing) or severe illness (you were hospitalized) due to COVID-19 or you have a weakened immune system, you need to isolate through day 10.

- Recommending that if you had severe illness or have a weakened immune system, consult your doctor before ending isolation. Ending isolation without a viral test may not be an option for you. If you are unsure if your symptoms are moderate or severe or if you have a weakened immune system, talk to a healthcare provider for further guidance.
- Clarifying that after you have ended isolation, if your COVID-19 symptoms worsen, restart your isolation at day 0. Talk to a healthcare provider if you have questions about your symptoms or when to end isolation.
- Recommending screening testing of asymptomatic people without known exposures will no longer be recommended in most community settings.
- Emphasizing that physical distance is just one component of how to protect yourself and others. It is important to consider the risk in a particular setting, including local COVID-19 Community Levels and the important role of ventilation, when assessing the need to maintain physical distance.

Actions to take will continue to be informed by the COVID-19 Community Levels, launched in February. CDC will continue to focus efforts on preventing severe illness and post-COVID conditions, while ensuring everyone have the information and tools, they need to lower their risk.

This updated guidance is intended to apply to community settings. In the coming weeks CDC will work to align stand-alone guidance documents, such as those for healthcare settings, congregate settings at higher risk of transmission, and travel, with today's update.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

CDC works 24/7 protecting America's health, safety and security. Whether disease start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC responds to America's most pressing health threats. CDC is headquartered in Atlanta and has experts located throughout the United States and the world.

Page last reviewed: August 11, 2022

Consolidated Department of Defense Coronavirus Disease 2019 Force Health Protection Guidance

This guidance issued by the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) presents a uniform and consolidated DoD policy for the Department's response to the coronavirus disease 2019 (COVID-19) pandemic and serves as the DoD COVID-19 Workplace Safety Plan.[1] Implementation of this guidance will comply with~~: 1) applicable court orders, Presidential directives, and Office of Management and Budget (OMB) and Safer Federal Workforce Task Force guidance; and 2)~~ applicable labor obligations to the extent such obligations do not hinder the DoD Components' ability to carry out their missions during this public health emergency. Prior delegations and exceptions made pursuant to the rescinded references remain valid unless rescinded by the authorizing official. Individual sections of this guidance will be updated as necessary by the USD(P&R). **Commanders and supervisors may implement additional, more stringent requirements with respect to masking and physical distancing, as appropriate, to mitigate risk.**

This guidance will be posted, and updated as necessary, at: https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/. DoD Components should monitor this website to obtain the most current version of this guidance. Changes from the previous version will be identified in bold and italics.

Furthermore, this guidance consolidates, incorporates, and rescinds the following policy and guidance:

- Secretary of Defense Memorandum, "Guidance for Commanders' Risk-Based Responses and Implementation of the Health Protection Condition Framework During the Coronavirus Disease 2019 Pandemic," April 29, 2021
- Secretary of Defense Memorandum, "Use of Masks and Other Public Health Measures," February 4, 2021
- Secretary of Defense Memorandum, "Updated Conditions-based Approach to Coronavirus Disease 2019 Personnel Movement and Travel Restrictions." March 15, 2021
- Secretary of Defense Memorandum, "Way Forward for SARS-CoV-2 Testing Within the Department of Defense," April 29, 2021
- Deputy Secretary of Defense Memorandum, "Updated Coronavirus Disease 2019 Guidance Related to Travel and Meetings," September 24, 2021
- Deputy Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of DoD Civilian Employees," October 1, 2021
- Under Secretary of Defense Memorandum, "Administrative Leave for Coronavirus Disease 2019 Vaccination of Department of Defense Employees," April 14, 2021
- Under Secretary of Defense Memorandum, "Force Health Protection Guidance for the Novel Coronavirus," January 30, 2020, and all supplements.

[1] Executive Order (EO) 13991, "Protecting the Federal Workforce and Requiring Mask-Wearing," January 20, 2021.

TABLE 1: Force Health Protection Measures by HPCON Level for the COVID-19 Pandemic

HPCON D Severe	**High COVID-19 Community Level* Risk, with degraded availability of medical countermeasures, and substantial loss of medical capability** **High COVID-19 Community Level* in the county in which the installation is located.** **AND any of the following** **Civilian healthcare capability and utilization (percent and trend)*:** >50 percent staffed of hospital beds filled with individuals who have COVID-19 as the primary admission criteria; or >70 percent of staffed intensive care unit (ICU) beds filled with individuals who have COVID-19 as the primary admission criteria; or Overall staffed hospitals and ICUs have limited to no capacity. **OR** **Military Health System (MHS) health care capability and utilization (percent and trend):** Degradation of MHS capabilities requiring Crisis Status operations; and >95 percent staffed bed occupancy; or >50 percent military medical treatment facility (MTF) staff in isolation or quarantine ~~**or unvaccinated**~~; or >60 percent staff absent who provide urgent or emergent care; and Local emergency departments on divert or inability of civilian health care to absorb excess MHS patients; or Clinical or appointment capability reduced >60 percent in key departments. **OR** **Other factors:** Loss of vaccine effectiveness in available vaccines resulting in vaccinated individuals routinely experiencing severe disease, hospitalization or death; or	**Utilize measures from HPCON A, B and C with the following modifications**: ~~**a. Less than 25 percent of normal occupancy in the workplace, or the minimum required on-site for essential operations that must be conducted in person.**~~ **a.** Strongly consider declaring a local Public Health Emergency. **b.** Consider limiting visitor access to the installation to only those required for mission essential activities. **c.** Cancel non-mission-essential activities. **d.** Close non-essential services (e.g., fitness centers, leisure and recreational facilities, beauty/barber shops, non-essential retail, dine-in eating establishments). **e.** Consider potential delay or cancelation of exercises. **f. Schools operated by Department of Defense Education Activity (DoDEA) will operate remotely.** **g.** Restrict or suspend social gatherings to the greatest extent possible. **h.** Follow any other applicable force health protection guidance at: https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.[12]

[12] For information about masking ~~**and screening testing**~~ at the various HPCON levels, refer to section~~**s 2.1 and**~~ 5.3.

SECTION 4: SURVEILLANCE AND SCREENING TESTING

4.1. ~~CONDUCTING REQUIRED SCREENING TESTING.~~ [RESCINDED]

~~To establish COVID-19 screening testing for individuals for whom weekly screening testing is required, DoD Components will:~~

a. ~~Execute the screening testing requirement with FDA approved or authorized COVID-19 self-collection kits or self-tests at least weekly (depending on the type of test kit used). Testing should be performed primarily onsite at the installation or facility with proper supervision and documentation of testing results. If onsite COVID-19 screening testing is not feasible, as an alternative self-testing may be performed at home or in other locations. (Note: these COVID-19 self-tests do not require a health care provider's clinical care order and are, therefore, considered an over-the-counter test and do not require medical support to complete).~~

   1. ~~COVID-19 self-tests must have Instructions for Use and FDA approval, 510(k) premarket clearance or have an FDA EUA. These tests will be made available through the DLA.~~

   2. ~~Funding for COVID-19 screening testing, if self-collection kits or self-tests are not available:~~

      i. ~~Each DoD Component will reimburse Service members and DoD civilian employees for COVID-19 screening tests that require payment for purposes of meeting the screening testing requirement (e.g., if the screening test is not available through the DoD Component and must be administered by a facility who charges for the test).~~

      ii. ~~For COVID-19 screening testing of DoD contractor personnel with CRA, DoD Components will offer, if available, COVID-19 screening testing similar to that offered to DoD civilian employees at the DoD Component's expense and at no cost to the contractor personnel or the contractor.~~

b. ~~Establish guidance for where and how these tests will be distributed and conducted, and how results are to be reported.~~

   1. ~~DoD civilian employees are responsible for providing documentation of negative COVID-19 test results, upon receipt, to the appropriate supervisor. For purposes of screening testing requirements, "supervisor" includes authorized human resources officials. DoD civilian employees may not be required to use their own personal equipment for the purpose of documenting test results; offsite tests may not be used if there is not a means to document results using Government equipment. The supervisor is~~

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND READINESS

JAN 30 2023

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Consolidated Department of Defense Coronavirus Disease 2019 Force Health Protection Guidance – Revision 4

Effective immediately, the preamble, executive summary, and sections 1.3, 1.4, 2.1, 3.3, 4.1-4.4, 5.1-5.5, 5.9-5.10, 5.12, 6, 7.1-7.7, and 9 of the "Consolidated Department of Defense – Coronavirus Disease 2019 Force Health Protection Guidance," (August 29, 2022 version) are amended as attached. The complete document with amendments is also available at https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/Latest-DOD-Guidance/.

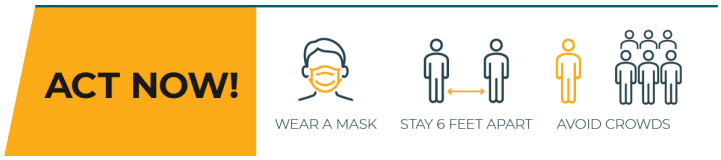
Where applicable, these changes end coronavirus disease 2019 (COVID-19) screening testing based on vaccination status; end the requirement to ask about COVID-19 vaccination status; update protocols for individuals exposed to someone with COVID-19; no longer require workplace occupancy limits for each Health Protection Condition levels; and modify travel guidance.

Components should engage with unions to ensure any bargaining obligations pursuant to chapter 71 of title 5, U.S. Code, are satisfied. Additionally, DoD Components should review in-place agreements and are encouraged to bring any conflicting provisions into compliance at the earliest possible opportunity.

Please direct any questions or comments to the following email address: dha.ncr.ha-support.list.policy-hrpo-kmc-owners@health.mil.

Gilbert R. Cisneros, Jr.

Attachment:
As stated



Workplace SARS-CoV-2 Testing: Consent Elements and Disclosures

Updated Jan. 21, 2021 Print

Purpose

SARS-CoV-2 testing may be incorporated as part of a comprehensive approach to reducing transmission in non-healthcare workplaces. This document describes the elements of consent and recommended disclosures necessary to support employee decision-making for participating in workplace-based testing. This document expands on the disclosures outlined in "SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces."

Overview: Consent and Supporting Employee Decision-Making

Workplace-based testing should **not** be conducted without the employee's informed consent. Informed consent requires disclosure, understanding, and free choice, and is necessary for an employee to act independently and make choices according to their values, goals, and preferences.

Differences in position and authority (i.e., workplace hierarchies), as well as employment status in non-standard working arrangements (e.g., temporary help, contract help, or part-time employment), can affect an employee's ability to make free decisions. To fully support employee decision-making and consent, employers should take the following measures when developing a testing program:

- Ensure safeguards are in place to protect an employee's privacy and confidentiality.
- Provide complete and understandable information about how the employer's testing program may impact employees' lives, such as if a positive test result or declination to participate in testing may mean exclusion from work.
- Explain any parts of the testing program an employee would consider especially important when deciding whether to participate. This involves explaining the key reasons that may guide their decision.
- Provide information about the testing program in the employee's preferred language using non-technical terms. Consider obtaining employee input on the readability of the information. Employers can use this tool to create clear

messages.

- Encourage supervisors and co-workers to avoid pressuring employees to participate in testing.
- Encourage and answer questions during the consent process. The consent process is active information sharing between an employer or their representative and an employee, in which the employer discloses the information, answers questions to facilitate understanding, and promotes the employee's free choice.

Disclosures for Workplace Testing

An employer's testing program (including the implementation of a testing protocol to test employees) may be complex and technical. Certain aspects of the testing program may be more relevant than others to an employee's decision whether to accept an offered test. SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces identifies disclosures important for employees contemplating testing. Many of these disclosures are addressed in the U.S. Food and Drug Administration (FDA) emergency use authorization patient fact sheet for the test, which must be provided during the consent process. Those disclosures include:

- The manufacturer and name of the test
- The test's purpose
- The type of test
- How the test will be performed
- Known and potential risks of harm, discomforts, and benefits of the test
- What it means to have a positive or negative test result, including:
  - Test reliability and limitations
  - Public health guidance to isolate or quarantine at home, if applicable

Additionally, an employer should be prepared to address the following topics:

General Considerations

- Why is the employer offering to test employees?
- How frequently will employees be tested, and will they be asked to consent to each test?
- What happens if an employee declines to be tested?

Scheduling and Payment

- Is the employee obligated to schedule the test and travel to the site?
- Will the employer pay for the employee's time and travel?
- Are there any available accommodations or alternatives for an employee who declines to take the test?
- Who pays for the test, including:
  - Will the employer pay for the test?

    Will the employee's insurance be billed for the test or will the employee

  - be billed for a copayment?
  - Will the employee pay for the test?
  - Will the employee's insurance be billed for follow-up care if needed?
  - Will the employee pay for follow-up care if needed?

Testing Site

- Who will be administering the test and what are their qualifications?
- Where will the test be performed?
- Will the test provider require any temperature and symptom screening prior to administering the test?

Communication and Interpretation of Results

- When will the results be provided to employees, and in what confidential manner?
- Who will interpret the test and what are their qualifications?
- The test provider's obligation to report a positive result to the public health authority.
- What happens if the employee tests positive, including:
  - Who will inform the employee about guidance for employee isolation and quarantine for those who have been around the employee?
  - Is there a need for follow-up testing?
  - Is there a need for medical evaluation?
  - Will the employer take any action, including any follow-up with the employee such as contact tracing?
  - When can the employee return to the work site?
  - Are there any flexible and supportive leave and other benefit policies available to the employee?
  - Will the employee be paid for any lost work time?
  - Will the employee's benefits be affected?
- What happens if the employee tests negative, including any need for follow-up testing?

Privacy

- What personal information does the employee need to provide (e.g., name, date of birth) to the test provider?
- Will that demographic information be retained, and if so, by whom and for how long?
- How will personal information be kept confidential and secure (i.e., restricted from unauthorized access or disclosure)?
- Which employer representative(s) will have access to the employee's result?
- Whether, where, and for how long will the employer retain the result?
- How will the employer keep the result confidential and secure?

Seeking Additional Help or Reporting Injuries

- Who to contact for additional information about the employer's testing program (e.g., an employer or union representative)?
- Who to contact to explain an employee's rights?
- Who to contact if assistance is needed (e.g., language translation or transportation to and from the testing site)?
- Will the employer provide treatment for any employee injuries from the test procedure and during transport to/from the testing site?

Last Updated Jan. 21, 2021
Content source: National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

The Wayback Machine - https://web.archive.org/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests

At-Home OTC COVID-19 Diagnostic Tests

Español (/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pruebas-de-covid-19-sin-receta-medica-o-de-venta-libre-para-diagnostico-en-el-hogar)



On this page:

- List of Authorized At-Home OTC COVID-19 Diagnostic Tests

This page has information about at-home over-the-counter (OTC) COVID-19 diagnostic tests. Diagnostic tests can show if you have an active COVID-19 infection.

These at-home COVID-19 diagnostic tests are FDA authorized (/web/20220805020652/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) for self-testing at home (or in other locations). This means you collect your own sample, perform the test, and read the result yourself without the need to send a sample to a laboratory. Authorized at-home OTC tests are available without a prescription and are typically available online or at local stores.

Testing and other protective steps like wearing a mask and COVID-19 vaccination are essential to stop the spread of COVID-19 infection.

For more information, including answers to frequently asked general questions about at-home COVID-19 diagnostic tests, visit At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions (/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions).

List of Authorized At-Home OTC COVID-19 Diagnostic Tests

The table below lists FDA-authorized at-home OTC COVID-19 diagnostic tests, and includes information on expiration dates, who can use the test, and other details that may help you decide what test is right for you.

The table includes links to home use instructions for each test. For more information about each test, including the Letter of Authorization and authorized labeling, see In Vitro Diagnostics EUAs: Tables of IVD EUAs (/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas).

In the table below, the "Expiration Date" column lists the shelf-life and where to find the expiration date for that test. The shelf-life is how long the test should work as expected and is measured from the date the test was manufactured. The expiration date is set at the end of the shelf-life. In some cases, the expiration date for a test may be extended. An extended expiration date means the manufacturer provided data showing that the shelf-life is longer than was

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known when the test was first authorized. For more information about how the expiration date is determined and why it may be extended, see the At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions (/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions).

To see if the expiration date for your at-home OTC COVID-19 test has been extended, first find the row in the below table that matches the manufacturer and test name shown on the box label of your test.

- If the Expiration Date column says that the shelf-life is "extended," there is a link to "updated expiration dates" where you can find a list of the original expiration dates and the new expiration dates. Find the original expiration date on the box label of your test and then look for the new expiration date in the "updated expiration dates" table for your test.
- If the Expiration Date column **does not** say the shelf-life is extended, that means the expiration date on the box label of your test is still correct. The table will say "See box label" instead of having a link to updated expiration dates.

The FDA will update this table as additional shelf-life extensions are authorized.

Search:

Show All entries

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Abbott Diagnostics Scarborough, Inc.: BinaxNOW COVID-19 Ag Card Home Test (/web/20220805020652/https://www.fda.gov/media/144575/download)  (/web/20220805020652/https://www.fda.gov/media/160087/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 15 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Requires supervision of a telehealth proctor and a smartphone or computer • Results in 15 minutes	• Shelf Life: 15 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580
Abbott Diagnostics Scarborough, Inc.: BinaxNOW COVID-19 Antigen Self Test (/web/20220805020652/https://www.fda.gov/media/147255/download)  (/web/20220805020652/https://www.fda.gov/media/160094/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 15 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Smartphone optional • Results in 15 minutes	• Shelf Life: 15 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Access Bio, Inc.: CareStart COVID-19 Antigen Home Test (/web/20220805020652/https://www.fda.gov/media/152188/download)  (/web/20220805020652/https://www.fda.gov/media/160095/download) Alternate brand name:  (/web/20220805020652/https://www.fda.gov/media/160097/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Smartphone optional • Alternate brand name: On/go COVID-19 Antigen Self-Test • Results in 10 minutes	• Shelf Life:12 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1587
ACON Laboratories, Inc: Flowflex COVID-19 Antigen Home Test (/web/20220805020652/https://www.fda.gov/media/152699/download)  (/web/20220805020652/https://www.fda.gov/media/160099/download) Alternate brand name:  (/web/20220805020652/https://www.fda.gov/media/160098/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Smartphone optional • Alternate brand name: On/Go One COVID-19 Antigen Home Test • Results in 15 minutes	• Shelf Life: 16 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580
Becton, Dickinson and Company (BD): BD Veritor At-Home COVID-19 Test (/web/20220805020652/https://www.fda.gov/media/151763/download)  (/web/20220805020652/https://www.fda.gov/media/160100/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Requires a smartphone • Results in 15 minutes	• Shelf Life: 6 months • Expiration Date: See box label

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Celltrion USA, Inc.: Celltrion DiaTrust COVID-19 Ag Home Test (/web/20220805020652/https://www.fda.gov/media/153421/download)  (/web/20220805020652/https://www.fda.gov/media/160101/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older	• Antigen test • Mid-turbinate nasal swab • Smartphone optional • Results in 15 minutes	• Shelf Life: 18 months (extended) • Expiration Date: See link for updated expiration dates (/web/20220805020652/https://www.fda.gov/media/1592
Cue Health Inc.: Cue COVID-19 Test for Home and Over The Counter (OTC) Use (/web/20220805020652/https://www.fda.gov/media/146471/download)  (/web/20220805020652/https://www.fda.gov/media/160102/download)	• People with or without symptoms	• Age 18 years and older • Age 2 years and older when collected by an adult	• Molecular test • Nasal swab • Requires a Cue Cartridge Reader (sold separately) • Requires a smartphone • Results in 20 minutes	• Shelf Life: 4 months • Expiration Date: See box label
Detect, Inc.: Detect Covid-19 Test (/web/20220805020652/https://www.fda.gov/media/153746/download)  (/web/20220805020652/https://www.fda.gov/media/160103/download)	• People suspected of COVID-19 • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Molecular test • Nasal swab • Requires a Detect Hub (sold separately) • Smartphone optional • Results in 60 minutes	• Shelf-Life: 8 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580
Ellume Limited: Ellume COVID-19 Home Test (/web/20220805020652/https://www.fda.gov/media/144593/download)  (/web/20220805020652/https://www.fda.gov/media/160104/download)	• People with or without symptoms	• Age 16 years and older • Age 2 years and older when collected by an adult	• Antigen test • Mid-turbinate nasal swab • Requires a Smartphone • Results in 15 minutes	• Shelf Life: 12 months • Expiration Date: See box label

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Genabio Diagnostics Inc.: Genabio COVID-19 Rapid Self-Test Kit (/web/20220805020652/https://www.fda.gov/media/159834/download)  (/web/20220805020652/https://www.fda.gov/media/160105/download)	• People with symptoms that began within the last 7 days. • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15-30 minutes	• Shelf Life: 18 months • Expiration Date: See box label
iHealth Labs, Inc.: iHealth COVID-19 Antigen Rapid Test (/web/20220805020652/https://www.fda.gov/media/153924/download)  (/web/20220805020652/https://www.fda.gov/media/160107/download) Alternate brand name:  (/web/20220805020652/https://www.fda.gov/media/160106/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 15 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Smartphone optional • Results in 15 minutes • Alternate brand name: GoodToKnow COVID-19 Antigen Rapid Test	• Shelf Life: 12 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580
InBios International Inc: SCoV-2 Ag Detect Rapid Self-Test (/web/20220805020652/https://www.fda.gov/media/154337/download)  (/web/20220805020652/https://www.fda.gov/media/160108/download)	• People with symptoms that began within the last 5 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 20 minutes	• Shelf Life: 13 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1580

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Lucira Health, Inc: Lucira CHECK-IT COVID-19 Test Kit (/web/20220805020652/https://www.fda.gov/media/147495/download)  (/web/20220805020652/https://www.fda.gov/media/160109/download)	• People with or without symptoms	• Age 14 years and older • Age 2 years and older when collected by an adult	• Molecular test • Nasal swab • Smartphone optional • Results in 30 minutes	• Shelf Life: 6 months • Expiration Date: See box label
Maxim Biomedical, Inc.: MaximBio ClearDetect COVID-19 Antigen Home Test (/web/20220805020652/https://www.fda.gov/media/155635/download)  (/web/20220805020652/https://www.fda.gov/media/160110/download)	• People with symptoms that began within the last 5 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15 minutes	• Shelf Life: 8 months (extended) • Expiration Date: See link for list of updated expiration date (/web/20220805020652/https://www.fda.gov/media/1605
OraSure Technologies, Inc.: InteliSwab COVID-19 Rapid Test (/web/20220805020652/https://www.fda.gov/media/149912/download)  (/web/20220805020652/https://www.fda.gov/media/160111/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 18 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Smartphone optional • Results in 30 minutes	• Shelf Life: 9 months • Expiration Date: See box label

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
OSANG LLC: OHC COVID-19 Antigen Self Test (/web/20220805020652/https://www.fda.gov/media/157549/download)  (/web/20220805020652/https://www.fda.gov/media/160112/download)	• People with symptoms that began within the last 7 days. The test is to be performed two times over three days (serial testing). • People without symptoms. The test is to be performed two times over three days (serial testing).	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15 minutes	• Shelf Life: 8 months • Expiration Date: See box label
PHASE Scientific International, Ltd.: INDICAID COVID-19 Rapid Antigen At-Home Test (/web/20220805020652/https://www.fda.gov/media/156955/download)  (/web/20220805020652/https://www.fda.gov/media/160113/download)	• People with symptoms that began within the last 6 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 20 minutes	• Shelf Life: 12 months • Expiration Date: See box label
Quidel Corporation: QuickVue At-Home OTC COVID-19 Test (/web/20220805020652/https://www.fda.gov/media/147250/download)  (/web/20220805020652/https://www.fda.gov/media/160114/download)	• People with symptoms that began within the last 6 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 10 minutes	• Shelf Life: 12 months • Expiration Date: See box label

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
SD Biosensor, Inc.: Pilot COVID-19 At-Home Test (/web/20220805020652/https://www.fda.gov/media/155126/download)  (/web/20220805020652/https://www.fda.gov/media/160115/download)	• People with symptoms that began within the last 6 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 20 minutes	• Shelf Life: 9 months (extended) • Expiration Date: See link for updated expiration date (/web/20220805020652/https://www.fda.gov/media/1596
Siemens Healthineer: CLINITEST Rapid COVID-19 Antigen Self-Test (/web/20220805020652/https://www.fda.gov/media/155176/download)  (/web/20220805020652/https://www.fda.gov/media/160116/download)	• People with symptoms that began within the last 7 days • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15 minutes	• Shelf Life: 11 months • Expiration Date: See box label
Watmind USA: Speedy Swab Rapid COVID-19 Antigen Self-Test (/web/20220805020652/https://www.fda.gov/media/159828/download)  (/web/20220805020652/https://www.fda.gov/media/160117/download)	• People with symptoms that began within the last 6 days. The test is to be performed two times over three days (serial testing) • People without symptoms. The test is to be performed two times over three days (serial testing)	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15 minutes	• Shelf Life: 6 months • Expiration Date: See box label

Manufacturer and Test Name (Links to Instructions for Use)	Who can use this test: Symptoms	Who can use this test: Age	Other Details	Expiration Date
Xiamen Boson Biotech Co., Ltd.: Rapid SARS-CoV-2 Antigen Test Card (/web/20220805020652/https://www.fda.gov/media/157545/download)  (/web/20220805020652/https://www.fda.gov/media/160118/download)	• People with symptoms that began within the last 6 days. The test is to be performed two times over three days (serial testing). • People without symptoms. The test is to be performed two times over three days (serial testing).	• Age 14 years and older • Age 2 years and older when collected by an adult	• Antigen test • Nasal swab • Results in 15 minutes	• Shelf Life: 6 months • Expiration Date: See box label

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Related information:

- At-Home COVID-19 Diagnostic Tests: Frequently Asked Questions (/web/20220805020652/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-covid-19-diagnostic-tests-frequently-asked-questions)
- COVID-19 Test Basics: (/web/20220805020652/https://www.fda.gov/consumers/consumer-updates/covid-19-test-basics) Includes details on COVID-19 tests, types of samples, and other information.
- What Is an EUA? (https://web.archive.org/web/20220805020652/https://www.youtube.com/watch?app=desktop&v=iGkwaESsGBQ&feature=youtu.be) (https://web.archive.org/web/20220805020652mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer) Video: Describes how the FDA can issue an emergency use authorization (EUA) to provide more timely access to diagnostic tests that may help during the public health emergency when there is no adequate, approved, and available alternative.

COVID-19 Tests Granted Traditional Marketing Authorization by the FDA

The FDA has been working with COVID-19 test developers seeking to pursue marketing authorization through the traditional premarket review pathways, which will allow these tests to continue to be used beyond the time allowed by emergency use authorization. This page lists COVID-19 tests that have received traditional marketing authorization. See the Marketing Your Device (/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device) page for more information about the traditional premarket review and authorization process.

Background

Initially, COVID-19 tests were only available under emergency use authorization (EUA) (https://www.youtube.com/watch?v=iGkwaESsGBQ) (http://www.fda.gov/about-fda/website-policies/website-disclaimer). Since the Secretary's 564 declaration related to in vitro diagnostic tests for COVID-19, on February 4, 2020, the FDA has granted EUAs for many COVID-19 tests. Tests with an active EUA can continue to be used as long as they are available and not expired. The FDA has also issued a guidance document with a Transition Plan for Medical Devices Issued EUAs Related to COVID-19 (/regulatory-information/search-fda-guidance-documents/transition-plan-medical-devices-issued-emergency-use-authorizations-euas-related-coronavirus-disease) and encourages EUA holders to pursue traditional marketing authorization. Visit the COVID-19 Test EUA page (/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas) for more information about these EUAs.

The EUA process is different than traditional clearance or approval of these products. The FDA may issue an EUA when the FDA has determined, based on the totality of scientific evidence available to the FDA, that it is reasonable to believe that the product may be effective for the intended use relevant to the emergency and that the known and potential benefits outweigh the known and potential risks of the product. This is different than the traditional device premarket review pathways, where the FDA considers whether there is a reasonable assurance of safety and effectiveness when the device is used as intended.

COVID-19 Tests Granted Traditional Marketing Authorization

CDRH remains committed to expanding access to safe and effective tests through the FDA's traditional premarket review pathway. The tables below list COVID-19 tests that have been granted marketing authorization by the FDA.

Molecular Diagnostic Tests

Search:

Show 100 entries

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Biofire Diagnostics, LLC	BioFire Respiratory Panel 2.1 (RP2.1)	Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M	03/17/2021	DEN200031 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN200031)
BioFire Defense, LLC	Biofire Covid-19 Test 2	RT, Nested multiplex PCR, Multiple Targets	H, M	07/25/2022	K221460 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221460) K211079 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K211079)
DiaSorin Molecular LLC	Simplexa Covid-19 Direct	Real-time RT-PCR, Multiple Targets	H, M	09/13/2022	K212147 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K212147)
BioFire Diagnostics	Biofire Spotfire Respiratory (R) Panel	Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M, W	02/03/2023	K213954 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213954)
DiaSorin Molecular LLC	Simplexa Covid-19 & Flu A/B Direct	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	03/17/2023	K220963 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220963)

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Biofire Diagnostics, LLC	Biofire® Spotfire® Respiratory (R) Panel Mini	Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M, W	04/13/2023	K230719 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230719)
Hologic, Inc.	Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay	Real-time RT-PCR, Multi-analyte	H	05/16/2023	K222736 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K222736)
Roche Molecular Systems, Inc.	cobas SARS-CoV-2 Qualitative for Use On The cobas 5800/6800/8800 Systems	Real-time RT-PCR, Multiple Targets	H, M	06/01/2023	K231306 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231306) K213804 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K213804) K240867 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K240867)
Roche Molecular Systems, Inc.	cobas® SARS-CoV-2 & Influenza A/B For Use On The cobas® Liat System	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	07/27/2023	K223591 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223591)
BD Integrated Diagnostic Solutions/Becton, Dickinson & Company	BD Respiratory Viral Panel for BD MAX™ System 445215; BD Respiratory Viral Panel-SCV2 for BD MAX™ System 445361	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	07/31/2023	K230956 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230956)
Abbott Diagnostics Scarborough, Inc.	ID NOW COVID-19 2.0	RT, Isothermal amplification, Single Target	H, M, W	08/10/2023	K221925 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K221925)
Cepheid	Xpert® Xpress CoV-2/Flu/RSV plus	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	08/17/2023	K231481 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K231481)
Cepheid	Xpert® Xpress CoV-2 plus	Real-time RT-PCR, Multiple Targets	H, M	10/13/2023	K230440 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230440)
Cue Health Inc.	Cue COVID-19 Molecular Test	Isothermal amplification, Over the Counter (OTC) Home Testing, Screening, Single Target	H, M, W, Home	11/28/2023	DEN220028 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN220028) K232643 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K232643)
Roche Molecular Systems, Inc.	cobas® SARS-CoV-2 Nucleic acid test for use on the cobas® Liat System	Real-time RT-PCR, Multiple Targets	H, M, W	12/04/2023	K223783 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223783)
Luminex Corporation	LIAISON PLEX Respiratory Flex Assay	RT-PCR, Multi-analyte, Multiple Targets	H, M	03/01/2024	K233410 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233410)

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Luminex Molecular Diagnostics, Inc.	NxTAG Respiratory Pathogen Panel v2 (NxTAG RPP v2)	RT-PCR, Multi-analyte, Multiple Targets	H	03/11/2024	K231758 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K231758)
BioFire Diagnostics, LLC	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel	Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M, W	03/26/2024	K232954 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232954)
QIAGEN GmbH	QIAstat-Dx Respiratory Panel Plus	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	05/10/2024	K233100 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233100)
BioFire Diagnostics, LLC	BIOFIRE SPOTFIRE Respiratory/Sore Throat (R/ST) Panel Mini	Nested multiplex PCR, Multi-analyte, Multiple Targets	H, M, W	05/30/2024	K241194 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K241194)
Life Technologies Corporation	Applied Biosystems™ TaqPath™ COVID-19 Diagnostic PCR Kit	Real-time RT-PCR, Multiple Targets	H	07/10/2024	K233453 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233453)
Hologic, Inc.	Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay	Real-time RT-PCR, Multiple Targets	H	07/18/2024	K241240 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241240)
QIAGEN GmbH	QIAstat-Dx Respiratory Panel Mini	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	10/25/2024	K242353 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242353)
Hologic, Inc.	Panther Fusion SARS-CoV-2/Flu A/B/RSV Assay	Real-time RT-PCR, Multiple Targets	H	11/15/2024	K242465 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242465)
Abbott Molecular	Alinity m SARS-CoV-2 AMP Kit (09N78-096); Alinity m SARS-CoV-2 CTRL Kit (09N78-086)	Real-time RT-PCR, Multiple Targets	H, M	12/06/2024	K241580 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241580)
Nuclein, LLC	DASH SARS-CoV-2 & Flu A/B Test	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	12/20/2024	K241652 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241652)
Life Technologies Corporation	Applied Biosystems TaqPath COVID-19, Flu A, Flu B, RSV Select Panel	Real-time RT-PCR, Multi-analyte, Multiple Targets	H	01/08/2025	K241806 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241806)
Cepheid	Xpert Xpress CoV-2/Flu/RSV plus	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M, W	01/10/2025	K242071 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242071)
Cepheid	Xpert® Xpress CoV-2 plus (XPRS-COV2-10)	Real-time RT-PCR, Multiple Targets	H, M, W	01/15/2025	K242109 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242109)

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Hologic, Inc.	Aptima SARS-CoV-2 Assay	TMA, chemiluminescent, Multiple Targets	H	02/13/2025	K243396 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K243396)
Abbott Molecular Inc.	Alinity m Resp-4-Plex	Real-time RT-PCR, Multi-analyte, Multiple Targets	H, M	02/14/2025	K241573 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241573)
Visby Medical, Inc.	Visby Medical Respiratory Health Test	RT-PCR, Multi-analyte, Multiple Targets	H, M, W	02/19/2025	K242526 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K242526)

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[1]Authorized setting(s) include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

Antigen Diagnostic Tests

Search:

Show 100 entries

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
ACON Laboratories, Inc.	Flowflex COVID-19 Antigen Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	11/09/2023	K230828 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230828)
Quidel Corporation	Sofia 2 SARS Antigen+ FIA; Sofia 2 SARS Antigen+ FIA Control Swab Set	Lateral Flow, Fluorescence, Instrument Read, Single Target	H, M, W	12/13/2023	DEN220039 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN220039) K233688 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233688)
Nano-Ditech Corporation	Nano-Check™ COVID-19 Antigen Test	Lateral Flow, Visual Read, Single Target	H, M	01/23/2024	K231187 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231187)
Quidel Corporation	QuickVue COVID-19 Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	03/22/2024	K231795 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K231795)
Healgen Scientific LLC	Healgen Rapid COVID-19 Antigen Test	Lateral Flow, Visual Read, Single Target	H, M	04/19/2024	K232377 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K232377)

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Acon Laboratories, Inc.	Flowflex Plus COVID-19 Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Test, Single Target	H, M, W, Home	04/19/2024	K233373 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233373)
IHealth Labs, Inc	iHealth COVID-19 Antigen Rapid Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	05/31/2024	K233842 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K233842)
CorDx, Inc.	CorDx Tyfast COVID-19 Ag Rapid Test; CorDx COVID-19 Ag Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	06/21/2024	K240728 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K240728)
InBios International, Inc.	SCoV-2 Ag Detect Rapid Test	Lateral Flow, Visual Read, Single Target	H, M, W	08/23/2024	K233358 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233358)
Guangzhou Wondfo Biotech Co., Ltd.	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	09/30/2024	K241317 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241317)
Healgen	Healgen Rapid Check COVID-19/Flu A&B Antigen Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	H, M, W, Home	10/07/2024	DEN240029 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN240029)
Osang LLC	QuickFinder COVID-19/Flu Antigen Self Test / QuickFinder COVID-19/Flu Antigen Pro Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	H, M, W, Home	01/13/2025	K243262 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K243262)
Wondfo USA Co., Ltd.	Welllife™ COVID-19 / Influenza A&B Home Test; Welllife™ COVID-19 / Influenza A&B AntigenTest	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Multi-analyte, Single Target	H, M, W, Home	01/16/2025	K243256 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K243256)
Access Bio, Inc.	CareSuperb™ COVID-19 Antigen Home Test	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	01/29/2025	K241915 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241915)

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Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Abbott Diagnostics Scarborough, Inc.	BinaxNOW™ COVID-19 Antigen Self Test; BinaxNOW™ COVID-19 Ag Card	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Single Target	H, M, W, Home	02/11/2025	K243518 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K243518)

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[1]Authorized setting(s) include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

Serology Tests

Search:

Show 100 entries

Manufacturer	Device Name	Attributes	Authorized Setting(s)[1]	Date of Authorization	Authorization
Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack, VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator	IgG	H, M	05/05/2023	DEN210038 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210038)
Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack, VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrators	Total Antibody	H, M	05/05/2023	DEN210040 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN210040)

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[1]Authorized setting(s) include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

These tables will be updated the Monday after a new test is granted marketing authorization and the 510(k) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm) and De Novo (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm) Premarket Databases have been updated.

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For information on EUAs granted to *in vitro* diagnostic tests for COVID-19, visit In Vitro Diagnostics EUAs (/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2).

Additional Resources

- FAQs: What happens to EUAs when a public health emergency ends? | FDA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends)
- FAQs on Emergency Use Authorizations (EUAs) for Medical Devices Related to COVID-19 | FDA (/medical-devices/covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-related-covid-19)
- Historical Information about Device Emergency Use Authorizations: In Vitro Diagnostics (IVD) (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

No. 22-40043

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

FEDS FOR MEDICAL FREEDOM; LOCAL 918, AMERICAN FEDERATION OF GOVERNMENT EMPLOYEES; HIGHLAND ENGINEERING, INCORPORATED; RAYMOND A. BEEBE, JR.; JOHN ARMBRUST; et al.,

Plaintiffs-Appellees,

v.

JOSEPH R. BIDEN, JR., in his official capacity as President of the United States; THE UNITED STATES OF AMERICA; PETE BUTTIGIEG, in his official capacity as Secretary of Transportation; DEPARTMENT OF TRANSPORTATION; JANET YELLEN, in her official capacity as Secretary of Treasury; et al.,

Defendants-Appellants.

On Appeal from the United States District Court
for the Southern District of Texas

OPENING BRIEF FOR APPELLANTS

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INTRODUCTION

Illness and death caused by Coronavirus Disease 2019 (COVID-19) have led to serious disruptions for American employers. Recognizing that vaccination lowers the risk of infection, serious disease, and death, many private employers have responded by requiring that their employees be vaccinated against COVID-19. The federal government did the same in its capacity as an employer. Exercising his constitutional and statutory authorities to oversee the Executive Branch, President Biden issued an Executive Order that directs federal agencies to require that current and new employees be vaccinated against COVID-19, subject to legally required exceptions for medical conditions or religious objections. *See* Exec. Order No. 14043, 86 Fed. Reg. 50,989 (Sept. 14, 2021).

A dozen district courts have denied requests to enjoin this Executive Order.[1] The district court in this case, however, issued a nationwide preliminary injunction

[1] *See Brnovich v. Biden*, No. CV-21-1568, 2022 WL 252396 (D. Ariz. Jan. 27, 2022); *Oklahoma v. Biden*, No. CIV-21-1136, 2021 WL 6126230 (W.D. Okla. Dec. 28, 2021); *Brass v. Biden*, No. 21-cv-2778, 2021 WL 6498143 (D. Colo. Dec. 23, 2021) (report and recommendation), *adopted*, 2022 WL 136903 (D. Colo. Jan. 14, 2022); *American Fed'n of Gov't Emps. Local 501 v. Biden*, No. 21-23828-CIV, 2021 WL 6551602 (S.D. Fla. Dec. 22, 2021); *Donovan v. Vance*, No. 21-CV-5148, 2021 WL 5979250 (E.D. Wash. Dec. 17, 2021); *McCray v. Biden*, No. 21-2882, 2021 WL 5823801 (D.D.C. Dec. 7, 2021); *Navy Seal 1 v. Biden*, No. 8:21-cv-2429, 2021 WL 5448970 (M.D. Fla. Nov. 22, 2021); *Rydie v. Biden*, No. 21-2696, 2021 WL 5416545 (D. Md. Nov. 19, 2021); *Altschuld v. Raimondo*, No. 21-cv-2779, 2021 WL 6113563 (D.D.C. Nov. 8, 2021); *Church v. Biden*, No. 21-2815, 2021 WL 5179215 (D.D.C. Nov. 8, 2021); *Smith v. Biden*, No. 1:21-cv-19457, 2021 WL 5195688 (D.N.J. Nov. 8, 2021); *Foley v. Biden*, No. 4:21-cv-1098, ECF No. 18 (N.D. Tex. Oct. 6, 2021).

No.

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS

v.

FEDS FOR MEDICAL FREEDOM, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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A. This Appeal Is Moot

The nationwide preliminary injunction issued by the district court and the government's appeal from that injunction became moot when the President revoked EO 14,043.

1. Under Article III, the jurisdiction of the federal courts is limited to the resolution of actual "Cases" or "Controversies." U.S. Const. Art. III, § 2, Cl. 1. "To qualify as a case fit for federal-court adjudication, 'an actual controversy must be extant at all stages of review.'" *Arizonans for Official English* v. *Arizona*, 520 U.S. 43, 67 (1997) (citation omitted). "A case that becomes moot at any point during the proceedings is 'no longer a "Case" or "Controversy" for purposes of Article III,' and is outside the jurisdiction of the federal courts." *United States* v. *Sanchez-Gomez*, 138 S. Ct. 1532, 1537 (2018) (quoting *Already, LLC* v. *Nike, Inc.*, 568 U.S. 85, 91 (2013)).

A case or appeal becomes moot "when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Already*, 568 U.S. at 91 (citation omitted). "No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute 'is no longer embedded in any actual controversy about the plaintiffs' particular legal rights.'" *Ibid.* (citation omitted).

Under those principles, this preliminary-injunction appeal became moot when the President revoked EO 14,043 and eliminated the basis for any agency policies premised on EO 14,043, such as the Safer Federal

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government agrees that *Munsingwear* vacatur is warranted there for the same reasons that it is warranted here and will convey that position in its response brief.

No. 22-1257, 2023 WL 4249469, at *1 (6th Cir. June 29, 2023); *Health Freedom Def. Fund* v. *President of the United States*, No. 22-11287, 2023 WL 4115990, at *2-*4 (11th Cir. June 22, 2023); *Missouri* v. *Biden*, No. 22-1104, 2023 WL 3862561, at *1 (8th Cir. June 7, 2023) (per curiam); *Hollis* v. *Biden*, No. 21-60910, 2023 WL 3593251, at *1 (5th Cir. May 18, 2023) (per curiam).

Even if revoking EO 14,043 in light of changed circumstances were viewed as akin to voluntarily ceasing to enforce it, this controversy would still be moot because the President "could not reasonably be expected" to reinstate EO 14,043. *Already, LLC*, 568 U.S. at 92 (citation omitted). A large majority of civilian federal employees already chose to become vaccinated against COVID-19. See EO 14,099, § 1, 88 Fed. Reg. at 30,891 (stating that the federal government had achieved "a 98 percent compliance rate," taking into account approved or pending exemptions). If the COVID-19 pandemic were to reenter an acute phase posing heightened dangers to the public and the civilian federal workforce, any policies adopted in response to those developments would be based on and responsive to those new circumstances. Likewise, any future challenge to those hypothetical policies would have to take into account the circumstances justifying them. At this time, no reasonable prospect exists that the government will resume enforcing the same policy challenged here.

B. The Decision Below Would Have Warranted Review

Vacatur of a lower court's decision because of intervening mootness is generally available only to "those who have been prevented from obtaining the review to which they are entitled." *Camreta* v. *Greene*, 563 U.S. 692, 712 (2011) (quoting *Munsingwear*, 340 U.S. at 39). It has therefore been the longstanding position of the

No. 23-60

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL., PETITIONERS

v.

FEDS FOR MEDICAL FREEDOM, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONERS

ELIZABETH B. PRELOGAR
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a. In some circumstances, a federal court may adjudicate an appeal that would otherwise be moot because a party faces "collateral legal consequences." *Lane* v. *Williams*, 455 U.S. 624, 632 (1982) (citation omitted). Respondents point to nothing like that here. They do not, for example, identify any "discipline" or "warning letters" received by any plaintiff before EO 14,043 was enjoined. Br. in Opp. 11. The district-court filings that respondents cite (*id.* at 12 n.8) do not contain any factual showing on those issues or any argument about collateral legal consequences. And even if respondents had made such a showing, this appeal would still be moot because only the preliminary injunction was at issue here—not any retrospective relief. Cf. *U.S. Navy SEALs 1-26* v. *Biden*, 72 F.4th 666, 672 (5th Cir. 2023) ("There is no need to enjoin policies that no longer exist.").

b. Respondents' reliance (Br. in Opp. 12-14, 20-24) on voluntary cessation is likewise misplaced. The President revoked EO 14,043 after determining that the pandemic had evolved such that "we no longer need a Government-wide vaccination requirement for Federal employees." EO 14,099, § 1, 88 Fed. Reg. at 30,891. The President's revocation of EO 14,043 because of changed circumstances is not akin to a governmental official voluntarily ceasing to enforce a challenged policy in order to evade review. Pet. 14-15. To the contrary, the circumstances here are much more analogous to those of *Munsingwear* itself, where the Court accepted that the government's suit to enforce wartime price controls had become moot when the government rescinded the price controls. See *Munsingwear*, 340 U.S. at 37-38; cf. *U.S. Bancorp Mortg. Co.* v. *Bonner Mall P'ship*, 513 U.S. 18, 25 n.3 (1994) (explaining that the "regulations sought to

Congress of the United States
Washington, DC 20510

September 15, 2022

The Honorable Lloyd J. Austin III
Secretary
U.S. Department of Defense
1300 Defense Pentagon
Washington, DC 20301

Dear Secretary Austin,

We write to express our grave concern over the effect of the Department of Defense's Covid-19 vaccine mandate on the readiness of our Armed Forces, particularly the U.S. Army. As a result of your mandate, eight percent of the Army's approximately 1 million soldiers face expulsion, Army recruiters cannot meet their FY22 target, and the Army has cut its projected FY23 end-strength by 12,000 soldiers.[1] As a major land war rages in Europe our own military faces a self-imposed readiness crisis.

Based on the sparse data published by the Department of Army, at least 40,000 National Guardsmen, 20,000 Army Reservists, and at least 15,000 Active Army Soldiers have yet to receive a Covid-vaccine and now face discharge.[2] The Department of Defense's own Covid response page indicates that approximately 900,000 soldiers are fully vaccinated out of the 1 million soldiers in the Army, Army Reserve, and Army National Guard.[3] However, during July testimony before the House Armed Services Committee, the Vice Chief of Staff of the Army claimed that fewer than 20,000 soldiers were unvaccinated.[4] The Army has not published updated data for months. The opaqueness of the Department continues to frustrate Members of

[1] In FY21, the U.S. Army contained 1,008,373 Soldiers. At least 84,000 face expulsion for not receiving a Covid-19 vaccine (8.3%), https://api.army.mil/e2/c/downloads/2022/02/22/58c0f9fe/army-profiles-fy21-tri-fold.pdf; The Army plans to cut 12,000 from its end-strength in FY23, https://federalnewsnetwork.com/army/2022/03/armys-2023-budget-will-remain-relatively-flat-temporarily-shrink-end-strength/; The Army has only met 40% of its FY22 recruiting goal, https://www.nbcnews.com/news/military/every-branch-us-military-struggling-meet-2022-recruiting-goals-officia-rcna35078.

[2] At least 40,000 National Guardsmen are unvaccinated along with 10% of the Army Reserve (18,000 or more Soldiers), https://apnews.com/article/covid-health-army-only-on-ap-government-and-politics-41f0f24bd26b2f8c4284e1fd396f88b8/gallery/60884872785c4533bd3a2440423b20e3; Army Data from June 2nd, 2022 suggests that 3.1% or more of the Active Army remains unvaccinated, https://www.army.mil/article/257228/department_of_the_army_announces_updated_covid_19_vaccination_statistics.

[3] Department of Defense Coronavirus; DoD Response Webpage, https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/, Current as of September 2nd, 2022.

[4] Testimony of Vice Chief of Staff of the Army, General Joseph M. Martin before the Readiness Subcommittee of the House Armed Services Committee on July 19th, 2022. https://armedservices.house.gov/2022/7/subcommittee-on-readiness-hearing-fiscal-year-2023-readiness-program-update

Congress attempting to perform oversight of the Executive Branch. Our repeated inquiries remain unanswered.

We are not the only ones frustrated. Thousands of these servicemembers have been left in limbo while they wait for the adjudication of religious and medical exemptions. Some have waited for nearly a year to learn if they will be forcibly discharged for their sincerely held religious beliefs or medical concerns. Most, if not all, of the small number of approved exemptions to date have gone to servicemembers in the process of leaving the Army.[5] Furthermore, according to current Army policy, even those few soldiers who receive permanent exemptions will be treated as second class soldiers for the rest of their careers— each of them requires approval from the Undersecretary of the Army to travel, change assignments, or even attend training courses away from their home station. The Department has abused the trust and good faith of loyal servicemembers by handling vaccine exemptions in a sluggish and disingenuous manner.

If 75,000 soldiers are discharged, it begs the question whether the Army will be able to replace them. As indicated in a House Armed Services Readiness Subcommittee hearing in July, the Army will need to make additional cuts in its end-strength, particularly in the Reserve Components, and it will have significant gaps in its operational capabilities.

At the very end of the fiscal year, the Army has only met 52% of its FY22 recruiting goal.[6] How will it recruit another 75,000 troops beyond its annual target to account for vaccine-related discharges? Earlier this summer, the service began accepting enlistees without high school degrees or GEDs, offering $35,000 to any enlistee willing to go to basic training within 45 days, removing tattoo policies, and allowing soldiers to pick their first duty station. We are not at war, but the Army is reducing basic standards and offering enlistment incentives greater than or equal to those during the height of the War on Terror--with poorer results.

We clearly see your vaccine mandate as the primary cause of the Department's recruiting difficulties. According to the Centers for Disease Control and Prevention, over forty percent of men aged 18-24 years old have refused vaccination for Covid-19.[7] In the Southern United States, an area responsible for half of the nation's enlistments, that number is over fifty percent.[8] Off the bat, your vaccine mandate disqualifies more than forty percent of the Army's target demographic from service nationwide, and over half of the individuals in the most fertile recruiting grounds.

In the past, you have insisted the Covid-19 vaccine mandate is an imperative for readiness, but increasing amounts of data raise legitimate questions about your assertion. Servicemembers under 40 years of age without comorbidities have nearly no chance of death from the virus, and

[5] Testimony of Secretary of the Army Christine Wormuth before the House Armed Services Committee on May 12th, 2022, https://armedservices.house.gov/hearings?ID=BC7D976E-87D8-47A4-B818-7711504FC4E9.

[6] https://www.nbcnews.com/news/military/army-far-recruited-half-soldiers-hoped-fiscal-2022-rcna42740

[7] https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends

[8] Only 49.1% of men aged 18-24 years old are fully vaccinated in the Southeast United States, https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends.

study after study has shown that covid vaccinations have negligible or even negative efficacy against the Omicron strains.[9] We also know that natural immunity provides better protection against infection and death than existing Covid vaccines, yet the Department still refuses to recognize it in lieu of vaccination.[10]

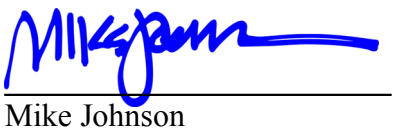
The data is now clear. The Department of Defense's Covid vaccine mandate is deleterious to readiness and the military's ability to fight and win wars. The vaccine provides negligible benefit to the young, fit members of our Armed Forces, and the mandate's imposition is clearly affecting the Department's ability to sustain combat formations and recruit future talent. *We urge you to immediately revoke your Covid-19 vaccine mandate for all servicemembers, civilian personnel, and contractors and re-instate those who have already been discharged.* Furthermore, we request the following information:

- How many soldiers remain unvaccinated by component, military occupational specialty (MOS), and years of service?
- How many soldiers have filed for religious, medical, and administrative exemptions?
- How many religious, medical, and administrative exemptions have been granted?
- How many airmen, sailors, and marines remain unvaccinated by component and Air Force Specialty Code (AFSC)/Rate/MOS?
- How much will it cost the Department to recruit, train, and PCS replacements for the soldiers facing expulsion for their failure to comply with the vaccine mandate?
- If all remaining unvaccinated soldiers are discharged and the Army continues recruiting at the same rate through the end of this fiscal year, what will be the projected FY23 end strengths of the Army, Army National Guard, and Army Reserve in six months?

Sincerely,

[9] According to CDC data, men between 18 to 29 years of age had a death rate of 78 per one million cases. This includes men with existing comorbidities which are largely absent in the military like obesity, cancer, diabetes, and hypertension, https://www.clevelandfed.org/en/newsroom-and-events/publications/cfed-district-data-briefs/cfddb-20220323-age-adjusted-covid-19-mortality-rates-by-demographic-groups.aspx; Fully vaccinated individuals experience negative or negligible immunity against Omicron infection, https://www.nejm.org/doi/full/10.1056/NEJMoa2203965; Both boosted and fully vaccinated individuals lose immunity over time, https://pubmed.ncbi.nlm.nih.gov/35249272/.

[10] Previous infection provides equivalent or better immunity to being fully vaccinated and boosted, https://www.nejm.org/doi/full/10.1056/NEJMoa2203965/.



Mike Johnson
Member of Congress



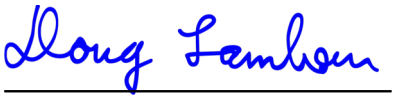
Chip Roy
Member of Congress



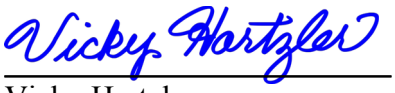
Thomas Massie
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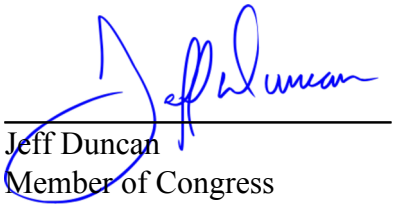
Elise M. Stefanik
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Doug Lamborn
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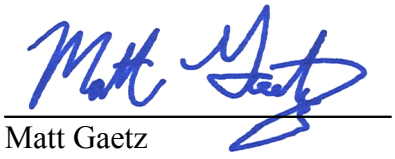
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Jeff Duncan
Member of Congress



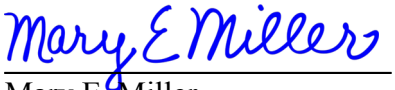
Scott DesJarlais, M.D.
Member of Congress



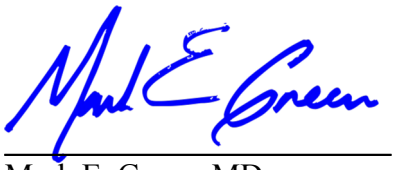
Matt Gaetz
Member of Congress



Dan Bishop
Member of Congress



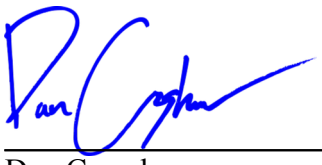
Mary E. Miller
Member of Congress



Mark E. Green, MD
Member of Congress



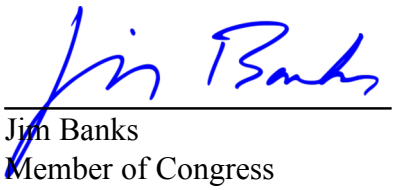
Louie Gohmert
Member of Congress



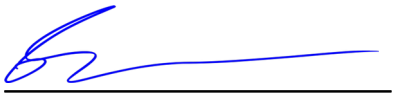
Dan Crenshaw
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Bill Posey
Member of Congress



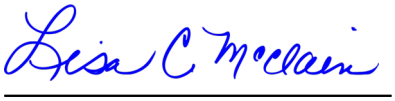
Jim Banks
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Brian J. Mast
Member of Congress



Lance Gooden
Member of Congress



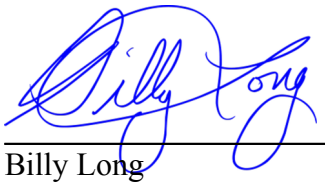
Lisa C. McClain
Member of Congress



Warren Davidson
Member of Congress



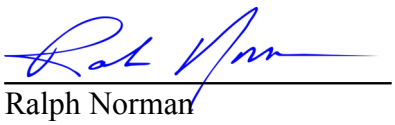
Bob Good
Member of Congress



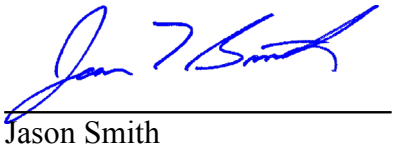
Billy Long
Member of Congress



Markwayne Mullin
Member of Congress



Ralph Norman
Member of Congress



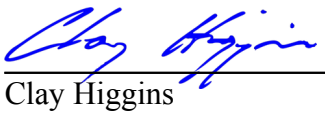
Jason Smith
Member of Congress



Jefferson Van Drew
Member of Congress



Richard Hudson
Member of Congress



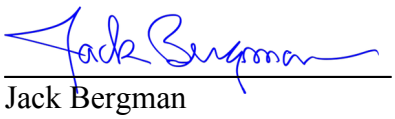
Clay Higgins
Member of Congress



Guy Reschenthaler
Member of Congress



Diana Harshbarger
Member of Congress



Jack Bergman
Member of Congress



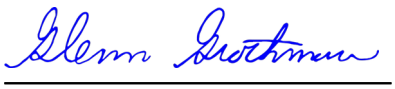
Ben Cline
Member of Congress



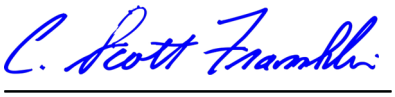
Tim Burchett
Member of Congress



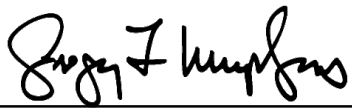
Andy Biggs
Member of Congress



Glenn Grothman
Member of Congress



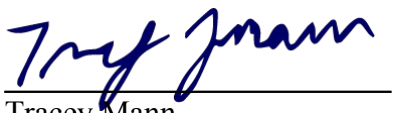
C. Scott Franklin
Member of Congress



Gregory F. Murphy, M.D.
Member of Congress



Garret Graves
Member of Congress



Tracey Mann
Member of Congress



Ronny L. Jackson
Member of Congress



Debbie Lesko
Member of Congress

Rick W. Allen
Member of Congress

Robert B. Aderholt
Member of Congress

John H. Rutherford
Member of Congress

Christopher H. Smith
Member of Congress

Pete Stauber
Member of Congress

W. Gregory Steube
Member of Congress

December 4, 2024

SELECT SUBCOMMITTEE ON THE

CORONAVIRUS PANDEMIC

CHAIRMAN BRAD WENSTRUP

AFTER ACTION REVIEW OF THE COVID-19 PANDEMIC:
The Lessons Learned and a Path Forward

Final Report of the

Select Subcommittee on the Coronavirus Pandemic
Committee on Oversight and Accountability

U.S. House of Representatives

BRAD R. WENSTRUP, D.P.M.
CHAIRMAN

ONE HUNDRED EIGHTEENTH CONGRESS

RAUL RUIZ, M.D.
RANKING MEMBER

Congress of the United States

House of Representatives

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

Majority (202) 225–5074
Minority (202) 225–5051

Dear Colleague:

It has been my distinct pleasure to lead the Select Subcommittee on the Coronavirus Pandemic for the 118th Congress. I was honored to be entrusted with a great responsibility: to investigate a once in 100-year pandemic and to prepare America for next time—and there will be a next time. This is a responsibility I took very seriously, and I believe that seriousness and teamwork has translated to much success.

Five years ago, on December 1, 2019, was what would eventually be the first confirmed case of COVID-19. After that, a pandemic devastated the world at nearly never before seen proportions, leaving millions dead and millions more concerned about long-term consequences.

COVID-19 was novel. The brightest scientists and medical experts were learning on the job to determine how to treat both the underlying disease and the second order side effects.

Since February 2023, the Select Subcommittee sought to produce a full after-action report to provide a road map of how we, in Congress, the Executive, and the private sector may better prepare for and respond to future pandemics. Throughout this process, the Select Subcommittee sent more than 100 investigative letters, conducted 38 transcribed interviews or depositions, held 25 hearings or meetings, and reviewed more than one million pages of documents from dozens of custodians. This work looks back on many events, comments, guidances, and other actions, to look forward. This is the single most thorough review of the pandemic conducted to date.

Most of you know me. You know I strive to work collegially, with our fellow Americans, to provide results for all of us. That is the same mentality I brought to my work as Chairman of the Select Subcommittee. During a time of intense partisanship, the Select Subcommittee had bipartisan consensus across multiple topics.

1) The possibility that COVID-19 emerged because of a laboratory or research related accident is not a conspiracy theory.

2) EcoHealth Alliance, Inc. and Dr. Peter Daszak should never again receive U.S. taxpayer dollars.

3) Scientific messaging must be clear and concise, backed by evidentiary support, and come from trusted messengers, such as front-line doctors treating patients.

4) Public health officials must work to regain American's trust; Americans want to be educated, not indoctrinated.

5) Former New York Governor Andrew Cuomo participated in medical malpractice and publicly covered up the total number of nursing home fatalities in New York.

In addition to these notable bipartisan successes, the Select Subcommittee developed extensive findings, some of which include:

1) The U.S. National Institutes of Health funded gain-of-function research at the Wuhan Institute of Virology.

2) The Chinese government, agencies within the U.S. Government, and some members of the international scientific community sought to cover-up facts concerning the origins of the pandemic.

3) Operation Warp Speed was a tremendous success and a model to build upon in the future. The vaccines, which are now probably better characterized as therapeutics, undoubtedly saved millions of lives by diminishing likelihood of severe disease and death.

4) Rampant fraud, waste, and abuse plagued the COVID-19 pandemic response.

5) Pandemic-era school closures will have enduring impact on generations of America's children and these closures were enabled by groups meant to serve those children.

6) The Constitution cannot be suspended in times of crisis and restrictions on freedoms sow distrust in public health.

7) The prescription cannot be worse than the disease, such as strict and overly broad lockdowns that led to predictable anguish and avoidable consequences.

Chairing the Select Subcommittee for the 118th Congress has been my honor. I said from the beginning, this work is the single most impactful responsibility I have undertaken in 12 years in Congress, and it has been. This work will help the United States, and the world, **predict** the next pandemic, **prepare** for the next pandemic, **protect** ourselves from the next pandemic, and hopefully **prevent** the next pandemic. Members of the 119th Congress should continue and build off this work, there is more information to find and honest actions to be taken.

The COVID-19 pandemic highlighted a distrust in leadership. Trust is earned. Accountability, transparency, honesty, and integrity will regain this trust. A future pandemic requires a whole of America response managed by those without personal benefit or bias. We can always do better, and for the sake of future generations of Americans, we must. It can be done!

Sincerely,



Brad Wenstrup, D.P.M.
Chairman

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VIII. While Testing for COVID-19 Was Flawed, Utilizing Public-Private Partnerships Resulted in Readily Available and Accurate Tests

Historically, the CDC has taken the lead on developing tests for new diseases and distributing the tests through the public health laboratory network.[1052] Once the genetic sequence of COVID-19 was identified, the CDC assumed initial responsibility for developing COVID-19 test kits.[1053] The agency produced a diagnostic test, which was distributed to public health laboratories in early February 2020.[1054] However, issues with the test's accuracy led to delays in widespread testing. The FDA began issuing EUAs[1055] in February 2020 to allow labs and manufacturers to develop, validate, and distribute COVID-19 tests.[1056] EUAs allowed for quicker deployment of tests without going through the typical, lengthier approval process.

As the CDC's tests were limited and, therefore, hindered testing capacity, the federal government encouraged private companies and laboratories to develop their own tests. In March 2020, commercial laboratories, such as Quest Diagnostics and LabCorp, were approved to develop and distribute tests, which significantly expanded testing capacity.[1057] Additionally, the federal government partnered with private industry to increase testing capabilities, including the launch of drive-through testing sites in collaboration with companies like Walmart, Walgreens, CVS, and others.[1058] The COVID-19 Testing Supply Chain Stabilization Task Force was also created to address shortages of testing materials.[1059]

In addition to developing and distributing tests, the federal government also issued testing guidance. Early on in March 2020, the CDC's testing guidelines prioritized people who were symptomatic, had traveled to affected areas, or were exposed to confirmed cases.[1060] Healthcare workers and those in critical roles were also prioritized due to limited testing capacity.[1061] As testing availability expanded by June of 2020, the CDC updated its guidelines to include asymptomatic individuals, especially those in high-risk settings like long-term care facilities or prisons.[1062] The guidance gradually shifted to encourage broader testing.

[1052] U.S. DEP'T OF HEALTH AND HUMAN SERVICES OFFICE OF INSPECTOR GENERAL, A-04-20-02027, *CDC's Internal Control Weaknesses led to its initial COVID-19 Test Kit Failure, but CDC Ultimately Created a Working Test Kit*, at 4-5 (Oct. 2023) [hereinafter "HHS IG report"].
[1053] *Id.* at 6.
[1054] *Id.*
[1055] See below, "The Review of Pfizer's Biologics License Application," pg. 311.
[1056] HHS IG report, *supra* note 1502, at 6, figure 2.
[1057] Noah Weiland & Katie Thomas, *Trump Administration Moves to Speed Coronavirus Testing*, THE N.Y. TIMES (Mar. 13, 2020).
[1058] Amy Goldstein, *et al., Trump says he will partner with private sector to expand coronavirus testing but details are sketchy*, THE WASH. POST (Mar. 13, 2020).
[1059] *FEMA COVID-19 Supply Chain Task Force: Supply Chain Stabilization*, FEMA.
[1060] Roni Caryn Rabib & Katie Thomas, *Coronavirus Testing Offered With Just a Doctor's Approval, C.D.C. Says,* THE N.Y. TIMES (Mar. 4, 2020).
[1061] Carolyn Y. Johnson, *et al., In hard-hit areas, testing restricted to health care workers, hospital patients*, THE WASH. POST (Mar. 21, 2020).
[1062] *COVID-19 timeline*, U.S. CTRS. FOR DISEASE AND CONTROL (June 13, 2020) (CDC releases consolidated guidelines for COVID-19 testing— including for nursing homes, long-term care facilities, and high-density critical infrastructure workplaces, like food production facilities.)

The federal government also provided funding to facilitate testing. There was significant financial support for testing through the CARES Act, which allocated billions of dollars for testing and disease surveillance.[1063] This funding helped expand testing sites, purchase testing supplies, and support state and local public health efforts. The Health Care Enhancement Act allocated an additional $25 billion for testing, including funds for states, territories, and tribes to develop testing plans and increase capacity.[1064]

FINDING:	Career Scientists at the U.S. Centers for Disease Control and Prevention Undermined Trust in Public Health by Overpromising and Underdelivering Early Testing Kits, Including Knowingly Putting Tests with a High Failure Rate on the Market Without Appropriate Disclosures.

In the early stages of the pandemic, states sent samples to the CDC, which then tested those samples in its labs.[1065] Although the CDC has limited capacity to conduct these tests, Dr. Redfield testified that samples from states were not refused by the CDC, albeit it may have taken several days to test those samples.[1066] States wanted their own test kits so that they could test their own samples, and the CDC sought to facilitate that request.

Dr. Redfield was not involved in the CDC's development of these test kits.[1067] In fact, Dr. Redfield testified that the CDC is "not a manufacturing company [and] had [he] been involved in those decisions at the time, [he] would have recommended a contract manufacturing company manufacture [the test kits]."[1068]

While the CDC's career scientists' desire to quickly develop these test kits was laudable, the execution was disastrous. These career scientists assured the public that reliable, widespread testing would soon be accessible, helping to contain outbreaks and protect public health.[1069] These officials opted to develop their own test kits rather than use tests already approved and distributed internationally[1070] or seek assistance from industry. This slowed the process significantly and prevented wider access to testing.

The CDC's first batch of COVID-19 test kits, distributed in February 2020, were found to be faulty due to contamination issues.[1071] These tests that were rushed to market without

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[1063] *See*, CARES Act, *supra* note 396.
[1064] *Id.*
[1065] Transcribed Interview of Robert Redfield, M.D., Former Dir., U.S. Ctrs. for Disease and Control, at 43 (Mar. 17, 2022).
[1066] *Id*.
[1067] *Id.* at 75 ("There were people at the states, obviously a number of them said it would be easier for them if they could do the tests themselves. And people at CDC had decided that they would try to facilitate that. And this is not something I was engaged in the decision making at the time. But the lab group and the incident command group decided that the lab team would develop reagents that then they would distribute to the public health labs.").
[1068] *Id.*
[1069] Arman Azad, *WHO and CDC never discussed providing international test kits to the US, global health agency says*, CNN (Mar. 18, 2020).
[1070] *Id*.
[1071] Dina Temple-Raston, *CDC Report: Officials Knew Coronavirus Test Was Flawed But Released It Anyway*, NPR (Nov. 6, 2020).

sufficient validation had high failure rates. These included both false positives and false negatives, which undermined the reliability of testing as a public health tool.[1072]

However, within weeks of distribution, it was discovered that the tests were producing inconclusive results due to a flaw in one of the components used in the chemical analysis (referred to as a "reagent") of the collected sample.[1073] This flaw led to a significant delay in the ability of public health labs to conduct tests, leaving the U.S. blind to the early spread of the virus. These issues led to delays in testing at a critical time when the virus was beginning to spread widely in the U.S. Despite the promises of widespread testing, many areas of the country faced severe shortages of tests, leading to long wait times for results and a lack of timely data to inform public health decisions. There were instances where CDC scientists did not fully disclose the limitations and failure rates of certain tests.[1074] For example, some tests that were approved by the FDA under EUAs were later found to be less accurate than initially reported.[1075]

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[1072] *Summary of the Findings of the Immediate Office of the General Counsel's Investigation Regarding CDC's Production of COVID-19 Test Kits*, DEP'T OF HEALTH AND HUMAN SERVICES (June 19, 2020) *available at* https://www.documentcloud.org/documents/6953861-6-19-20-Summary-of-the-Findings-of-the-Immediate.html.
[1073] *Id*.
[1074] Dan Vergano, *The Government Asked Us Not To Release Records From The CDC's First Failed COVID Test. Here They Are*, BUZZFEED NEWS (Dec. 8, 2021).
[1075] *Id.*

that the FDA should be completely insulated from. Dr. Woodcock readily admitted this fact during her transcribed interview.

> **Dr. Janet Woodcock (May 13, 2024)**
>
> Q. Does the FDA have any role in shaping policies like vaccine mandates?
>
> A. No.[1243]

FINDING: U.S. Food and Drug Administration Officials Refused to Rebut Allegations the Biden White House Was Involved in the Pfizer Biologics Approval Application.

On August 9, 2021, after Dr. Marks had taken over the review of the Pfizer BLA but prior to it being completed, Secretary Austin issued a memo which announced his intention to seek President Biden's approval to mandate COVID-19 vaccines for U.S. servicemembers "no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first."[1244] As indicated by the memo, Secretary Austin was unable to issue a mandate for COVID-19 vaccines without a waiver from President Biden so long as the vaccines remained under EUA status.[1245] The memo implies that Secretary Austin was aware that the FDA had been working with an ADD of September 15, 2021. Additionally, the DOD's press release announcing this memo denotes that "the Food and Drug Administration is expected to give full approval to the vaccines, possibly by the end of the month."[1246]

Ultimately, the FDA issued its approval for Pfizer's BLA on August 23, 2021, and the very next day, on August 24, 2021, Secretary Austin issued a memo announcing the DOD's vaccine mandate.[1247] The dubious timing raises concerns about whether Secretary Austin, or any other executive branch official, may have been involved in the hyper-acceleration of the ADD. Dr. Krause testified that he thought it appeared that some decisions that OVRR would normally make were being made elsewhere:

> **Dr. Philip Krause (September 7, 2023)**
>
> I admit that the events in July and August surrounding the BLA and the booster vaccines made me concerned, without direct knowledge of any

[1243] Woodcock TI, *supra* note 1171, at 96-97
[1244] Memorandum from Lloyd Austin, Sec'y of Defense, to All Dept's of Defense Employees, *Message to the Force* (Aug. 9, 2021).
[1245] Wen. W. Shen, CONG. RESEARCH SERVS., R46745, *State and Federal Authority to Mandate COVID-19 Vaccination* (May 17, 2022) (in the military context, for instance, additional waiver requirements under 10 U.S.C. § 1107a may apply to the administration of medical products subject to EUAs to servicemembers.)
[1246] Jim Garamone, *Biden to Approve Austin's Request to Make COVID-19 Vaccine Mandatory for Service Members*, DOD NEWS (Aug. 9, 2021).
[1247] Memorandum from Lloyd Austin, Sec'y of Defense, to Senior Pentagon Leadership, Commanders of the Combatant Commanders, Defense Agency and DOD Field Activity Directors, Rescission of August 24, 2021 and November 30, 2021 Coronavirus Disease 2019 Vaccination Requirements for Members of the Armed Forces (Jan. 10, 2023).

> Our analysis strongly suggests that mandatory COVID-19 vaccine policies have had damaging effects on public trust, vaccine confidence, political polarization, human rights, inequities and social wellbeing. We question the effectiveness and consequences of coercive vaccination policy in pandemic response and urge the public health community and policymakers to return to non-discriminatory, trust-based public health approaches.[1335]

The BMJ paper also found that COVID-19 vaccine mandates primarily served to encourage vaccination in younger people who were the least at-risk for serious COVID-19 illness, and that this further entrenched distrust and provoked reactance:

> Although studies suggest that current policies are likely to increase population-level vaccination rates to some degree, gains were largest in those under 30 years old (a very low-risk group) and in countries with below average uptake. Moreover, insights from behavioral psychology suggest that these policies are likely to entrench distrust and provoke *reactance*—a motivation to counter an unreasonable threat to one's freedom.[1336]

Dr. Bardosh testified before the Select Subcommittee during a July 27, 2023 hearing titled "Because I Said So: Examining the Science and Impact of COVID-19 Vaccine Mandates." Dr. Bardosh was able to further expand on these findings on COVID-19 vaccine mandates.

> **Dr. Kevin Bardosh (July 27, 2023)**
>
> Q. Dr. Bardosh, let's amplify some of the points from your publications. There was a collaborative effort that you published with researchers and physicians from Johns Hopkins, Harvard, and Oxford, yes or no?
>
> A. Yes.
>
> Q. Did the COVID vaccine mandates from your research, from your publication with others, erode civil liberties?
>
> A. Yes, it did.
>
> Q. Did the COVID vaccine mandates fracture trust in public health officials?
>
> A. Yes, it did.

[1335] Bardosh, The unintended consequences of COVID-19 vaccine policy, *supra* note 891.
[1336] *Id.*

information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Community Infrastructure Program Grant Proposals; OMB Control Number 0704–0607.

Type of Request: Revision.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden per Response: 15 hours.

Annual Burden Hours: 2,250.

Needs and Uses: Section 2391(d) of Title 10, United States Code (10 U.S.C. 2391), authorizes the Secretary of Defense to, ''make grants, conclude cooperative agreements, and supplement funds available under Federal programs administered by agencies other than the Department of Defense, for projects owned by a State or local government, or a not-for-profit, member-owned utility service to address deficiencies in community infrastructure supportive of a military installation.'' The Consolidated Appropriations Act for Fiscal Year 2021 (Pub. L. 116–260) provided $60 million to the Office of Local Defense Community Cooperation (OLDCC) for the Defense Community Infrastructure Program (DCIP). This information collection supports the awarding of grants under DCIP via the initial grant proposal package prepared in accordance to a Federal Funding Opportunity Announcement posted on the *Grants.gov* website. The criteria established for the selection of community infrastructure projects reflects projects consisting of some combination of attributes that will enhance: (i) Military value; (ii) military installation resilience; and/or, (iii) military family quality of life at a military installation. Respondents can be State or local governments and not-for-profit, member-owned utility services owning infrastructure outside of, but supporting, a military installation.

Affected Public: State, Local or Tribal Government; Not-for-profit Institutions.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27677 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0126]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 22, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Human Resources Activity, 4800 Mark Center Drive, Suite 08F05, Alexandria, VA 22350, LaTarsha Yeargins, 571–372–2089.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: COVID–19 Vaccination Attestation Form; DD Form 3150; OMB Control Number 0704–0613.

Needs and Uses: DoD is seeking approval of the collection of information addressed by DD Form 3150 ''Certification of Vaccination''. This information is being requested in order to promote the safety of individuals in Federal buildings and on DoD installations, consistent with the COVID–19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force and guidance from the CDC and the Occupational Safety and Health Administration and all applicable government FAQs pertaining to the government's response to COVID 19. This information will be used by DoD staff charged with implementing and enforcing workplace safety protocols and is required for ensuring compliance with the requirement for attestation by all civilian employees, on-site contractors, and official visitors. Individuals who refuse to comply with any associated requirements based on the responses to DD Form 3150 may be

refused access to the Federal or DoD installation or facility to which access is sought.

Affected Public: Individuals or households.

Annual Burden Hours: 116,667 hours.

Number of Respondents: 3,500,000.

Responses per Respondent: 1.

Annual Responses: 3,500,000.

Average Burden per Response: 2 minutes.

Frequency: On occasion.

Dated: December 16, 2021.

Kayyonne T. Marston,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27685 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2021–OS–0096]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by January 21, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, (571) 372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Mandatory Disclosures as Part of Limitations on Terms of Consumer Credit Extended to Service Members and Dependents; OMB Control Number 0704–0444.

Type of Request: Extension.

Number of Respondents: 37,500.

Responses per Respondent: 6,347 average (varies widely by type of respondent).

Annual Responses: 238,012,500.

Average Burden per Response: 30 seconds.

Annual Burden Hours: 1,983,438 hours.

Needs and Uses: Title 10 U.S.C. 987, as established by section 670 of the National Defense Authorization Act for Fiscal Year 2007 and as amended by sections 661–663 of the National Defense Authorization Act for Fiscal Year 2013, establishes limitations on terms of consumer credit extended to members of the Armed Forces and their dependents. The purpose of this information collection is to ensure disclosures required by 10 U.S.C. 987(c)(1) and discretionary checks of covered-borrower status stipulated in 32 CFR 232.5(b)(2) by creditors in the process of extending consumer credit.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: December 16, 2021.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2021–27676 Filed 12–21–21; 8:45 am]

BILLING CODE 5001–06–P

ELECTION ASSISTANCE COMMISSION

Sunshine Act Meetings

AGENCY: Election Assistance Commission.

ACTION: Sunshine Act notice; notice of public meeting agenda.

SUMMARY: Public Meeting: U.S. Election Assistance Commission Local Leadership Council Meeting.

DATES: Tuesday, January 11, 2022 1:00 p.m.–2:30 p.m. Eastern.

ADDRESSES: Virtual via Zoom.

The meeting is open to the public and will be livestreamed on the U.S. Election Assistance Commission YouTube Channel: *https://www.youtube.com/channel/UCpN6i0g2rlF4ITWhwvBwwZw.*

FOR FURTHER INFORMATION CONTACT: Kristen Muthig, Telephone: (202) 897–9285, Email: *kmuthig@eac.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: In accordance with the Government in the Sunshine Act (Sunshine Act), Public Law 94–409, as amended (5 U.S.C. 552b), the U.S. Election Assistance Commission (EAC) will conduct a virtual meeting of the EAC Local Leadership Council.

Agenda: The U.S. Election Assistance Commission (EAC) Local Leadership Council will be discussing National Poll Worker Recruitment Day and soliciting feedback to make this effort as effective as possible. The Members will also be discussing the organization structure of the Local Leadership Council, EAC resources, and the Election Administration and Voting Survey (EAVS).

Background: The Local Leadership Council was established in June 2021 under agency authority pursuant to and in accordance with the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2). The Advisory Committee is governed by the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees. The Advisory Committee shall advise the EAC on how best to fulfill the EAC's statutory duties set forth in 52 U.S.C. 20922 as well as such other matters as the EAC determines. It shall provide a relevant and comprehensive source of expert, unbiased analysis and recommendations to the EAC on local election administration topics to include but not limited to voter registration, voting system user practices, ballot administration (programming, printing, and logistics), processing, accounting, canvassing, chain of custody, certifying results, and auditing.

The Local Leadership Council consists of 100 members. The Election Assistance Commission appoints two members from each state after soliciting nominations from each state's election official professional association. At the time of submission, the Local Leadership Council has 88 appointed

Dated: February 7, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–03004 Filed 2–10–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2022–HA–0019]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Health Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by April 12, 2022.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Terry McDavid, 703–681–3645.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Statement of Personal Injury: Possible Third Party Liability; DD Form 2527; OMB Control Number 0720–0003.

Needs and Uses: When a claim for TRICARE benefits is identified as involving possible third party liability and the information is not submitted with the claim, the TRICARE contractors request that the injured party (or a designee) complete DD Form 2527. To protect the interests of the U.S. Government, the contractor suspends claims processing until the requested third party liability information is received. The contractor conducts a preliminary evaluation based upon the collection of information and refers the case to a designated appropriate legal officer of the Uniformed Services. The responsible Uniformed Services legal officer uses the information as a basis for asserting and settling the U.S. Government's claim. When appropriate, the information is forwarded to the Department of Justice as the basis for litigation.

Affected Public: Individuals or households.

Annual Burden Hours: 47,022.5.

Number of Respondents: 188,090.

Responses per Respondent: 1.

Annual Responses: 188,090.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: February 7, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–03003 Filed 2–10–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2021–OS–0126]

Submission for OMB Review; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by March 14, 2022.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: COVID–19 Vaccination Attestation Form; DD Form 3150; OMB Control Number 0704–0613.

Type of Request: Revision.

Number of Respondents: 1,200,000.

Responses per Respondent: 1.

Annual Responses: 1,200,000.

Average Burden per Response: 2 minutes.

Annual Burden Hours: 40,000 hours.

Needs and Uses: DoD is seeking approval of the collection of information addressed by DD Form 3150 ''Certification of Vaccination''. This information is being requested in order to promote the safety of individuals in Federal buildings and on DoD installations, consistent with the COVID–19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force and guidance from the CDC and the Occupational Safety and Health Administration and all applicable government FAQs pertaining to the government's response to COVID–19. This information will be used by DoD staff charged with implementing and enforcing workplace safety protocols and is required for ensuring compliance with the requirement for attestation by all civilian employees, on-site contractors, and official visitors. Individuals who refuse to comply with any associated requirements based on the responses to DD Form 3150 may be denied access to the Federal or DoD installation or facility to which access is sought.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: February 7, 2022.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2022–02989 Filed 2–10–22; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Federal Perkins Loan, Federal Work-Study, and Federal Supplemental Educational Opportunity Grant Programs; 2022–23 Award Year Deadline Dates

In notice document 2022–01897 beginning on page 4871 in the issue of Monday, January 31, 2022, make the following correction:

On page 4872, in the table, under the heading ''What is the deadline for submission?'', entry five should read ''Tuesday, November 1, 2022.''.

[FR Doc. C1–2022–01897 Filed 2–10–22; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF EDUCATION

[Docket No.: ED–2022–SCC–0011]

Supplemental Support Under the American Rescue Plan (SSARP) Application; Correction

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Correction notice.

On February 8, 2022, the U.S. Department of Education published a correction notice in the **Federal Register** (Vol. 87, No 26, Page 7163, Column 2) seeking to correct the public comment period closing date for an information collection entitled, ''Supplemental Support under the American Rescue Plan (SSARP) Application.'' The Docket Number for the correction (ED–2020–SCC–0011), is incorrect, and the correct Docket Number is ED–2022–SCC–0011.

The PRA Coordinator, Strategic Collections and Clearance, Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: February 8, 2022.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Office of the Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2022–02997 Filed 2–10–22; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–431–A]

Application To Export Electric Energy; Tenaska Power Services Co.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Tenaska Power Services Co. (Applicant or TPS) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before February 28, 2022.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

FOR FURTHER INFORMATION CONTACT: Matt Aronoff, 202–586–5863, *matthew.aronoff@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On November 3, 2021, TPS filed an application with DOE (Application or App.) ''for renewal of its blanket authorization to transmit electric energy from the United States to Mexico for a period of five years.'' App. at 1. TPS states that it ''is authorized to do business in the State of Nebraska and such other states as required by the current nature of its business,'' adding that it ''is a power marketer authorized by the Federal Energy Regulatory Commission (FERC) to make sales of electric power at wholesale in interstate commerce at market-based rates.'' *Id.* TPS represents that it ''does not own or control any transmission facilities and does not have a franchised service area.'' *Id.*

TPS further claims that it would ''purchase the electricity that it may export, on either a firm or an interruptible basis, from wholesale generators, electric utilities, federal power marketing agencies and affiliates through negotiated agreements that have been voluntarily executed by the selling parties after considering their own need for any such electricity.'' App. at 3. TPS contends that its ''proposed electricity exports will not impair or tend to impede the sufficiency of electric power supplies in the United States or the regional coordination of electric utility planning or operations.'' App. at 3–4.

TPS applied to renew the authorization granted in DOE Order No. EA–431, which expired on January 26, 2022. Due to an unexpected delay in processing the renewal application, DOE has not yet evaluated whether the application satisfies the requirements of FPA section 202(e). TPS has requested expedited treatment of its application, to avoid any continued lapse in its export authority and to minimize the disruption to its electricity trade. TPS has also indicated that it has not engaged in the export of electricity since its authorization expired and will not do so unless and until it receives an Order granting renewal of its export authority in this proceeding. In response to TPS's request for expedited treatment, DOE has shortened the public comment period to 15 days.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the FERC Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to

transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Nurse Faculty Loan Program—Program Specific Data Form	90	1	90	8	720
Nurse Faculty Loan Program—Annual Performance Report Financial Data Form	260	1	260	6	1,560
Total Burden	350		350		2,280

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–02408 Filed 2–6–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Determination of Public Health Emergency

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV). On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of this novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination and declaration took effect February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, 21 U.S.C. 360bbb–3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act [1] sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.[2]

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met.

The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) by the Secretary of HHS, as described below, enable the FDA Commissioner to issue EUAs for certain in vitro diagnostics for emergency use under section 564 of the FD&C Act. The Centers for Disease Control and Prevention (CDC) requested that the FDA issue an EUA for its in

[1] 42 U.S.C. 247d–6b.

[2] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Public Law 113–5, the Secretary may make determination of a public health emergency, or a significant potential for a public health emergency, under section 564 of the FD&C Act. The Secretary is no longer required to make a determination of a public health emergency in accordance with section 319 of the PHS Act, 42 U.S.C. 247d to support a determination or declaration made under section 564 of the FD&C Act.

vitro diagnostic for detection of 2019-nCoV to allow the Department to take preparedness measures based on information currently available about 2019-nCoV.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

III. Declaration of the Secretary of Health and Human Services

Also on February 4, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus (2019-nCoV), I declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the novel coronavirus (2019-nCoV) pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of any EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–02496 Filed 2–6–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, April 16, 4:00 p.m. to April 17, 2020, 5:00 p.m., Bethesda North Marriott Hotel & Conference Hotel, 5701 Marinelli Road, Rockville, MD, 20850 which was published in the **Federal Register** on January 30, 2020, 85 FR 5456.

This meeting notice is amended to change the meeting dates and start and end times. The meeting will now be held on April 15, 2020, 3:00 p.m. to April 16, 2020, 6:00 p.m. The meeting is closed to the public.

Dated: February 3, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–02402 Filed 2–6–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Review the U01 Diversity Program Consortium—Dissemination and Translation Award applications.

Date: March 25, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites—Chevy Chase Pavilion, Conference Room Chevy Chase Ballroom, 4300 Military Road NW, Washington, DC 20015.

Contact Person: Rebecca H. Johnson, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN18C, 45 Center Drive, Bethesda, MD 20892, (301) 594–2771, *johnsonrh@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: February 3, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–02406 Filed 2–6–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, February 27, 2020, 11:00 a.m. to 3:00 p.m., National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, MD 20850 which was published in the **Federal Register** on December 30, 2019, 84 FR 71964.

This meeting notice is amended to change the meeting start time from 11:00 a.m. to 10:00 a.m. on February 27, 2020. The meeting is closed to the public.

Dated: February 3, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–02401 Filed 2–6–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cellular, Molecular and Integrative Reproduction Study Section, February 19, 2020, 8:00 a.m. to February 20, 2020, 5:00 p.m. at the Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314, which was published in the **Federal Register** on January 27, 2020, 85 FR 4672.

The Contact Person for this meeting has been changed to Elaine Sierra-Rivera, Ph.D., Scientific Review Officer, Phone (301) 435–1053, email: *riverase@csr.nih.gov.* The meeting date and time remain the same. The meeting is closed to the public.

delegated herein prior to the effective date of this delegation.

Robert McGowan,

Chief of Staff, CDC.

[FR Doc. 2020–06471 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ryan White HIV/AIDS Treatment Extension Act of 2009: Update to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed To Include Coronavirus Disease 2019 (COVID–19), the Disease Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2)

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is adding coronavirus disease 2019 (COVID–19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), to the *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed.* The list and companion guidelines are published by NIOSH pursuant to the Ryan White HIV/AIDS Treatment Extension Act of 2009. NIOSH encourages medical facilities to review the agency's guidelines describing the manner in which medical facilities should make determinations on whether an emergency response employee was exposed to COVID–19, the disease caused by SARS–CoV–2.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Office of the Director, NIOSH; 1090 Tusculum Avenue, MS:C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Pub. L. 101–381) was reauthorized in 1996, 2000, 2006, and 2009. The most recent reauthorization, the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87), amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii) and, pursuant to Section 2695, requires the HHS Secretary to establish the following: A list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which emergency response employees (ERE) may be exposed while responding to emergencies; guidelines describing circumstances in which EREs may be exposed to these diseases, taking into account the conditions under which emergency response is provided; and guidelines describing the manner in which medical facilities should make determinations about exposures to EREs.

In a **Federal Register** notice published on July 14, 2010, the HHS Secretary delegated this responsibility to the CDC Director.[1] The CDC Director further assigned the responsibility to the NIOSH Director and formally re-delegated the authority to develop the list and guidelines to NIOSH on August 27, 2018.[2]

Addition of COVID–19, the Disease Caused by the Virus SARS–COV–2, to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

The list of potentially life-threatening infectious diseases maintained by NIOSH is available in a **Federal Register** notice published on November 2, 2011 (76 FR 67736), available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.* With this notice the NIOSH *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is updated by the addition of the following:

C. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means

■ COVID–19 (the disease caused by the virus SARS–CoV–2)

COVID–19, the disease caused by the virus SARS–CoV–2, is being added to the existing list. COVID–19, the disease caused by the virus SARS–CoV–2, is a potentially life-threatening emerging infectious disease that is thought to be spread primarily by respiratory droplets generated by an infectious person through events such as coughing or sneezing (*https://www.cdc.gov/coronavirus/2019-ncov/index.html*).

EREs may be exposed to COVID–19, the disease caused by the virus SARS-CoV–2, by a victim of an emergency who may be infected with SARS–CoV–2 while attending to, treating, assisting, or transporting the victim to a medical facility. Medical facilities should review the NIOSH guidelines describing the manner in which medical facilities should make determinations about exposures to life-threatening infectious diseases, including COVID–19, available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2020–06458 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human

[1] 75 FR 40842.

[2] 83 FR 50379 (October 4, 2018).

Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, 21 U.S.C. 360bbb–3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for certain medical devices to allow the Department to take response measures based on information currently available about the virus that causes COVID–19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of certain medical devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for these devices for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

III. Declaration of the Secretary of Health and Human Services

On March 24, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, SARS–CoV–2, I declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: March 24, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–06541 Filed 3–25–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Review Subcommittee Member Conflict Review Panel.

Date: April 7, 2020.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Suite 2118, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Philippe Marmillot, Ph.D., National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 301–443–2861 *marmillotp@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: June 8, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Room B, Bethesda, MD 20817.

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch Office of Extramural Activities National Institute on Alcohol Abuse and Alcoholism, 6700b Rockledge Drive, Room 2120, MSC 6902 Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 11, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 12, 2020.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06747 Filed 3–31–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

AGENCY: Department of Health and Human Services.

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 27, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for drugs and biological products to allow the Department to take response measures based on information currently available about the virus that causes COVID–19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of drugs and biological products by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for drugs and biological products for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

III. Declaration of the Secretary of Health and Human Services

On March 27, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, I declared that circumstances exist justifying the authorization of emergency use of drugs

and biological products during the COVID–19 pandemic, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: March 27, 2020.

Alex M. Azar II,

Secretary.

[FR Doc. 2020–06905 Filed 3–30–20; 2:00 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Board of Regents, May 12–13, 2020, 9:00 a.m. to 4:00 p.m. at the National Institutes of Health, Building 38, Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892 which was published in the **Federal Register** on February 4, 2020, 85 FR 23, Page 6210.

This notice is being amended to change the meeting location from the National Institutes of Health, Building 38, Lindberg Room, 8600 Rockville Pike, Bethesda, MD 20892 to a virtual meeting. The URL link to this meeting is: *https://videocast.nih.gov.* Any member of the public may submit written comments no later than 15 days after the meeting.

Dated: March 27, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–06768 Filed 3–31–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Health Informatics and Health Care Delivery.

Date: April 10, 2020.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Dr., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428, *wup4@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 26, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–06766 Filed 3–31–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Investigator-Initiated Clinical Trial Planning Grant (R34).

Date: April 23, 2020.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G41, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Kelly L. Hudspeth, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Room 3G41, Rockville, MD 20852, 240–669–5067, *kelly.hudspeth@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 26, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–06765 Filed 3–31–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 19–059: Global Noncommunicable Diseases and Injury Across the Lifespan (R21).

Date: April 10, 2020.

Time: 10:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Weijia Ni, Ph.D., Chief/Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3100,

10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: March 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–05641 Filed 3–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Security Assistant Deputy Secretary of National Security Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Deputy Secretary for National Security within the Office of the Secretary (OS), Immediate Office of the Secretary (IOS), Office of National Security (ONS), the authorities vested in me as the Secretary of Health and Human Services for managing the Controlled Unclassified Information Program under Executive Order 13556, now and hereafter.

This authority may be redelegated, but only within ONS. Exercise of this authority shall be in accordance with established policies, procedures, guidelines, and regulations as prescribed by the E.O. 13556 and 32 CFR part 2002 ''Controlled Unclassified Information.''

This delegation of authority is effective immediately upon signature.

Dated: March 15, 2023.

Xavier Becerra,

Secretary.

[FR Doc. 2023–05637 Filed 3–17–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

COVID–19 Emergency Use Authorization Declaration

ACTION: Notice of amendment.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On March 15, 2023, the Secretary amended the February 4, 2020 determination made pursuant to section 564 of the FD&C Act and determined pursuant to his authority under section 564(b)(1)(C) that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad and that involves a biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2).

DATES: The section 564(b)(1)(C) determination that was originally issued on February 4, 2020, is amended as of March 15, 2023.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack: 202–260–0365, *paige.ezernack@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, an unlicensed biological product, or an unapproved animal drug; or (2) an unapproved use of an approved drug, approved or cleared device, licensed biological product, or conditionally approved animal drug. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a chemical, biological, radiological, or nuclear (''CBRN'') agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a CBRN agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then issue a declaration(s) that circumstances exist that justify the issuance of an EUA(s), at which point the FDA Commissioner may issue an EUA(s) for certain products if the criteria for issuance under section 564 of the FD&C Act are met. The section 564 declaration(s) terminate only when the Secretary of HHS determines that the termination requirements of section 564(b)(2)(A) of the FD&C Act are met. Additionally, section 564(b)(3) provides that the Secretary shall provide advance notice, by publication in the **Federal Register**, that a declaration(s) under section 564 will be terminated.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to his authority under section 564 of the FD&C Act, the Secretary of HHS determined that the circumstances in section 564(b)(1) exist because ''there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV).'' 85 FR 7316.

It is now well established that SARS–CoV–2 is constantly evolving and continues to be an ongoing challenge. As of January 30, 2023, SARS–CoV–2 has led to over 753 million cases of COVID–19, including 6.8 million deaths worldwide. This is due, in part, to variations in the virus that may allow it to spread more easily or make it resistant to treatments or decreased vaccine effectiveness. There is also a risk that eventually a variant will emerge that will escape the protection provided by the current generation of vaccines against severe disease. For example, the SARS–CoV–2 Omicron variant has continued to evolve into sublineages with additional mutations in the spike glycoprotein and the

receptor binding domain. Evolution of the virus also raises similar concerns about the continued efficacy of certain categories of therapeutics, such as monoclonal antibodies. The distribution of Omicron sublineages varies at different points in time in different regions of the world. The large number of mutations in the Omicron variant sublineages and the ongoing evolution of the virus remain a concern for potential evasion of vaccine immunity.

In light of this, I have now amended the February 4, 2020 determination to recognize the fact that there is ''a public health emergency, *or a significant potential for a public health emergency,* that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad'' and that involves a biological agent, namely the novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV, or SARS–CoV–2). (Emphasis added). If the current conditions change such that there is no longer a ''public health emergency'' within the meaning of section 564, the section 564(b)(1)(C) determination would remain in place because I have determined that there is also a ''significant potential for a public health emergency'' under that section. This avoids the need to issue a new determination under section 564 when there is no longer a ''public health emergency,'' but there is still a ''significant potential for a public health emergency'' involving SARS–CoV–2.

The four previously-issued section 564 declarations that refer to the February 4, 2020 determination have not been terminated by the Secretary because, among other things, the circumstances described in section 564(b)(1) continue to exist—*i.e.,* COVID–19, a disease attributable to SARS–CoV–2, continues to present a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad. Consistent with section 564(f), the currently-in-effect Emergency Use Authorizations (EUAs) issued under those section 564 declarations remain in effect until the earlier of the termination of relevant section 564 declarations under section 564(b), or revocation of the EUAs. Therefore, these EUAs continue in effect.

III. Declarations of the Secretary of Health and Human Services; EUAs Issued Under the Declarations

Based on the February 4, 2020 determination, in February and March 2020, the Secretary of HHS, pursuant to section 564 of the FD&C Act and subject to the terms of any authorization issued under that section, declared that circumstances exist justifying the authorization of emergency use of: (1) in vitro diagnostics for detection and/or diagnosis of this novel coronavirus, 85 FR 7316; (2) personal respiratory protective devices, 85 FR 13907; (3) other medical devices including alternative products used as medical devices, 85 FR 17335; and (4) drugs and biological products, 85 FR 18250.

These section 564 declarations continue in effect. Specifically, under section 564(b)(2)(A), a declaration made under section 564 will not terminate unless the Secretary determines that ''the circumstances described in [section 564(b)(1)] have ceased to exist,'' or there is ''a change in the approval status of the [authorized] product such that the circumstances described in subsection (a)(2) have ceased to exist.'' Section 564(b)(2)(A) of the FD&C Act. The first basis for termination is not met because the circumstances described in section 564(b)(1) have not ceased to exist; to the contrary, as described above, I have determined that the circumstances described in section 564(b)(1)(C) continue to exist. The second basis for termination is not met because each declaration covers many products, or emergency uses of products, at least some of which remain ''unapproved'' within the meaning of section 564(a)(2).

Consistent with section 564(f), the EUAs issued under these declarations remain in effect until the earlier of the termination of relevant section 564 declarations or revocation of the EUAs. Accordingly, the currently-in-effect EUAs issued under the section 564 determination/declarations for COVID–19 also continue in effect.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–05609 Filed 3–17–23; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Care Quality Across the Lifespan.

Date: March 28, 2023.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mary Kate Baker, DRPH, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–5117, *katie.baker2@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 15, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–05631 Filed 3–17–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to

(Slip Opinion)

Whether Section 564 of the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization

Section 564(e)(1)(A)(ii)(III) of the Food, Drug, and Cosmetic Act concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for a vaccine that is subject to an emergency use authorization.

July 6, 2021

MEMORANDUM OPINION FOR THE
DEPUTY COUNSEL TO THE PRESIDENT

Section 564 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3,[1] authorizes the Food and Drug Administration ("FDA") to issue an "emergency use authorization" ("EUA") for a medical product, such as a vaccine, under certain emergency circumstances. This authorization permits the product to be introduced into interstate commerce and administered to individuals even when FDA has not approved the product for more general distribution pursuant to its standard review process. Section 564 directs FDA—"to the extent practicable" given the emergency circumstances and "as the [agency] finds necessary or appropriate to protect the public health"—to impose "[a]ppropriate" conditions on each EUA. FDCA § 564(e)(1)(A). Some of these conditions are designed to ensure that recipients of the product "are informed" of certain things, including "the option to accept or refuse administration of the product." *Id.* § 564(e)(1)(A)(ii)(III).

Since December 2020, FDA has granted EUAs for three vaccines to prevent coronavirus disease 2019 ("COVID-19"). In each of these authorizations, FDA imposed the "option to accept or refuse" condition by requiring the distribution to potential vaccine recipients of a Fact Sheet that states: "It is your choice to receive or not receive [the vaccine]. Should you decide not to receive it, it will not change your standard medical care." *E.g.*, FDA, Fact Sheet for Recipients and Caregivers at 5 (revised June 25, 2021), https://www.fda.gov/media/144414/download

[1] Because it is commonly referred to by its FDCA section number, and for the sake of simplicity, we will refer to this provision as section 564, rather than by its United States Code citation.

("Pfizer Fact Sheet"). In recent months, many public and private entities have announced that they will require individuals to be vaccinated against COVID-19—for instance, in order to attend school or events in person, or to return to work or be hired into a new job. We will refer to such policies as "vaccination requirements," though we note that these policies typically are conditions on employment, education, receipt of services, and the like rather than more direct legal requirements.[2]

In light of these developments, you have asked whether the "option to accept or refuse" condition in section 564 prohibits entities from imposing such vaccination requirements while the only available vaccines for COVID-19 remain subject to EUAs. We conclude, consistent with FDA's interpretation, that it does not. This language in section 564 specifies only that certain information be provided to potential vaccine recipients and does not prohibit entities from imposing vaccination requirements.[3]

I.

A.

Federal law generally prohibits anyone from introducing or delivering for introduction into interstate commerce any "new drug" or "biological product" unless and until FDA has approved the drug or product as safe and effective for its intended uses. *See, e.g.*, FDCA §§ 301(a), 505(a), 21 U.S.C. §§ 331(a), 355(a); 42 U.S.C § 262(a). A vaccine is both a drug and a biological product. *See* FDCA § 201(g), 21 U.S.C § 321(g); 42 U.S.C. § 262(i)(1). Consistent with section 564, we will generally refer to it here as a "product." *See* FDCA § 564(a)(4)(C) (defining "product" to mean "a drug, device, or biological product").

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[2] For an example of the latter, see our discussion in Part II.B of a hypothetical military order to service members.

[3] We do not address whether other federal, state, or local laws or regulations, such as the Americans with Disabilities Act ("ADA"), might restrict the ability of public or private entities to adopt particular vaccination policies. *See, e.g.*, Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (updated June 28, 2021), https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws (discussing the ADA).

In 2003, Congress addressed a problem raised in emergency situations where "the American people may be placed at risk of exposure to biological, chemical, radiological, or nuclear agents, and the diseases caused by such agents," but where, "[u]nfortunately, there may not be approved or available countermeasures to treat diseases or conditions caused by such agents," even though "a drug, biologic, or device is highly promising in treating [such] a disease or condition." H.R. Rep. No. 108-147, pt. 1, at 2 (2003). President George W. Bush had flagged this problem in his 2003 State of the Union Address, in which he proposed Project BioShield, a legislative initiative "to quickly make available effective vaccines and treatments against agents like anthrax, botulinum toxin, Ebola, and plague." *Address Before a Joint Session of the Congress on the State of the Union* (Jan. 28, 2003), 1 Pub. Papers of Pres. George W. Bush 82, 86 (2003). Among the principal components of the proposed Project BioShield legislation were provisions to enable FDA to authorize medical products for use during emergencies even before they are proven to be safe and effective under ordinary FDA review. *See, e.g.*, H.R. 2122, 108th Cong. § 4 (2003). At that time, the only alternative to ordinary FDA approval was 21 U.S.C. § 355(i), which authorizes FDA to exempt drugs from the ordinary approval requirements where the drug is "intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." Such a cabined investigational new drug ("IND") exemption does not, however, allow the widespread dissemination of a drug for general public use in response to an emergency. *See* H.R. Rep. No. 108-147, pt. 1, at 2.

Congress enacted a version of the Project BioShield legislation's EUA provision in the National Defense Authorization Act for Fiscal Year 2004 as section 564 of the FDCA. *See* Pub. L. No. 108-136, § 1603(a), 117 Stat. 1392, 1684 (2003) (codified at 21 U.S.C. § 360bbb-3).[4] Section 564 authorizes the Secretary of Health and Human Services ("HHS")—who has delegated to FDA the authorities under the statute at issue here—to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency even though the product has not yet been generally approved as safe and

[4] The statute has been amended since, including when Congress enacted the Project BioShield Act the following year. *See* Pub. L. No. 108-276, § 4(a), 118 Stat. 835, 853 (2004).

effective for its intended use. FDCA § 564(a)(1)–(2); *see also* FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* at 3 n.6 (Jan. 2017) ("EUA Guidance") (noting delegation of most of the Secretary's authorities under section 564 to FDA).[5]

The most pertinent part of section 564 for purposes of your question has remained materially the same since Congress first enacted the statute in 2003. Subsection (e)(1)(A),[6] titled "Required conditions," provides:

> With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable [emergency] circumstances . . . , shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including [certain specified conditions].

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[5] The current version of section 564(a)(1) provides in full:

> Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act, and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

The "declaration under subsection (b)" refers to a declaration by the Secretary "that the circumstances exist justifying" an EUA, which must be made "on the basis" of one or more types of emergencies or threats. FDCA § 564(b)(1). FDA can grant an EUA where, "based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available," FDA finds that "it is reasonable to believe," among other things, that "the product may be effective in diagnosing, treating, or preventing" a "serious or life-threatening disease or condition" caused by a "biological, chemical, radiological, or nuclear agent or agents" (a standard less onerous than for final approval of the product); that "the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product"; and that "there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition." FDCA § 564(c).

[6] Subsection (e)(1) applies to a product that FDA has not approved as safe and effective for any intended use, whereas subsection (e)(2) applies to an unapproved use of an otherwise approved product. The COVID-19 vaccines fall under the former category, but the statute applies the condition at issue here to the latter category as well. *See* FDCA § 564(e)(2)(A).

The statute then lists a number of such conditions, including "[a]ppropriate conditions designed to ensure that individuals to whom the product is administered are informed" of certain information. FDCA § 564(e)(1)(A)(ii). This information includes the fact that FDA "has authorized the emergency use of the product," "the significant known and potential benefits and risks of such use," and "the extent to which such benefits and risks are unknown." *Id.* § 564(e)(1)(A)(ii)(I)–(II). Most relevant here, section 564(e)(1)(A)(ii)(III) directs FDA to impose conditions on an EUA "designed to ensure that individuals to whom the product is administered are informed . . . of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks."

In the same section of the 2004 National Defense Authorization Act, Congress also enacted another provision, codified as 10 U.S.C. § 1107a, which is specific to the U.S. military and which expressly refers to the "option to accept or refuse" condition described in section 564(e)(1)(A)(ii)(III). Pub. L. No. 108-136, sec. 1603(b)(1), § 1107a, 117 Stat. at 1690. Subsection (a) of this law provides that when an EUA product is administered to members of the armed forces, "the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President" and "only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(1).

B.

In the years after Congress enacted section 564, FDA issued dozens of EUAs in response to various public-health emergencies. *See, e.g.*, Authorization of Emergency Use of the Antiviral Product Peramivir Accompanied by Emergency Use Information; Availability, 74 Fed. Reg. 56,644 (Nov. 2, 2009) (antiviral drug to treat swine flu). The agency's use of EUAs increased dramatically with the onset of the COVID-19 pandemic in 2020. As of January 2021, the agency had issued more than 600 EUAs for products to combat COVID-19, including drugs, tests, personal protective equipment, and ventilators. *See* FDA, *FDA COVID-19 Pandemic*

instance, certain schools will require vaccination in order for students to attend class in person, and certain employers will require vaccination as a condition of employment.

Some have questioned whether such entities can lawfully impose such requirements in light of the fact that section 564 instructs that potential vaccine recipients are to be informed that they have the "option to accept or refuse" receipt of the vaccine.[8] In the past few months, several lawsuits have also been filed challenging various entities' vaccination requirements on the same theory.[9] The only judicial decision to have addressed this issue so far summarily rejected the challenge. *See Bridges v. Houston Methodist Hosp.*, No. 4:21-cv-01774, 2021 WL 2399994, at *1–2 (S.D. Tex. June 12, 2021), *appeal docketed*, No. 21-20311 (5th Cir. June 14, 2021).

II.

A.

We conclude that section 564(e)(1)(A)(ii)(III) concerns only the provision of information to potential vaccine recipients and does not prohibit public or private entities from imposing vaccination requirements for vaccines that are subject to EUAs. By its terms, the provision directs only that potential vaccine recipients be "informed" of certain information, including "the option to accept or refuse administration of the product."

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vaccine for new employees, Reuters (May 14, 2021, 9:16 AM), https://www.reuters.com/world/us/delta-will-require-covid-19-vaccine-new-employees-2021-05-14/.

[8] *See, e.g.*, Letter for Thomas C. Galligan Jr., Interim President, Louisiana State University, from Jeff Landry, Attorney General of Louisiana (May 28, 2021); *see also* Advisory Committee on Immunization Practices, Summary Report at 56 (Aug. 26, 2020), https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-08-508.pdf (reporting a CDC official as saying that EUA vaccines are not allowed to be mandatory).

[9] *See, e.g.*, Defendant's Notice of Removal, *Bridges v. Methodist Hosp.*, No. 4:21-cv-01774 (S.D. Tex. June 1, 2021), 2021 WL 2221293 (referencing complaint); Complaint, *Neve v. Birkhead*, No. 1:21-cv-00308 (M.D.N.C. Apr. 16, 2021), 2021 WL 1902937; Complaint, *Cal. Educators for Med. Freedom v. L.A. Unified Sch. Dist.*, No. 21-cv-2388 (C.D. Cal. Mar. 17, 2021), 2021 WL 1034618; Complaint, *Legaretta v. Macias*, No. 2:21-cv-00179 (D.N.M. Feb. 28, 2021), 2021 WL 909707; *see also* Complaint, *Health Freedom Defense Fund v. City of Hailey*, No. 1:21-cv-00212-DCN (D. Idaho May 14, 2021), 2021 WL 1944543 (making a similar argument about a face-mask requirement).

in the Fact Sheets are limited to consequences related to medical care). As we have noted, however, section 564 does not limit the ability of entities to impose vaccination requirements, and FDA would not be required to change the Fact Sheets in order to allow them to impose such requirements.[14]

* * * * *

As noted above, FDA agrees with our interpretation of section 564. On a few occasions, however, FDA has made statements that could be understood as saying that the condition described in section 564(e)(1)(A)(ii)(III) prohibits entities (particularly the U.S. military) from requiring the use of EUA products. In 2005, for instance, FDA issued an EUA that permitted the use of a vaccine for the prevention of inhalation anthrax by individuals between 18 and 65 years of age who were deemed by the Department of Defense ("DOD") to be at heightened risk of exposure due to an attack with anthrax. As a condition of that authorization, the agency required DOD to inform potential vaccine recipients "of the option to accept or refuse administration of [the vaccine]." Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability, 70 Fed. Reg. 5452, 5455 (Feb. 2, 2005). That EUA continued:

> With respect to [the] condition . . . relating to the option to accept or refuse administration of [the vaccine], the [immunization program] will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation

[14] FDA further informs us that, wholly apart from FDA's own authority to change the Fact Sheet, nothing in the FDCA would prohibit an administrator of the vaccine who also has a relationship with the individuals to whom the vaccine is offered (e.g., students in a university that offers the vaccine) from supplementing the FDA Fact Sheet at the point of administration with factually accurate information about the possible nonmedical consequences of the person choosing not to use the product (e.g., that she might not be permitted to enroll).

> based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

Id.; *see also id.* (allowing DOD to inform recipients that "military and civilian leaders strongly recommend anthrax vaccination, but . . . individuals [subject to the vaccination program] may not be forced to be vaccinated" and that "the issue of mandatory vaccination will be reconsidered by [DOD] after FDA completes its administrative process."). FDA included the same information in its later extension of that EUA. *See* Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Extension; Availability, 70 Fed. Reg. 44,657, 44,659–60 (Aug. 3, 2005).

In addition, although it is less than clear, certain FDA guidance could be read as saying that section 564 confers an affirmative "option" or "opportunity" to refuse EUA products. *See* EUA Guidance at 24 n.46 (implying that the condition in section 564(e)(1)(A)(ii)(III)—which is subject to waiver for the armed forces under 10 U.S.C. § 1107a—protects "the option for members of the armed forces to accept or refuse administration of an EUA product"); *Guidance Emergency Use Authorization of Medical Products*, 2007 WL 2319112, at *15 (July 1, 2007) (stating that "[r]ecipients must have an opportunity to accept or refuse the EUA product").

These statements do not affect our conclusion. Neither the 2005 anthrax vaccine EUA nor the later FDA guidance articulated a legal interpretation of section 564(e)(1)(A)(ii)(III)'s text. And FDA appears to have insisted upon the voluntariness requirement for DOD in the anthrax vaccine EUA because of then-recent litigation in which a court enjoined DOD from implementing a mandatory vaccination program based upon a different statutory provision that is inapplicable to EUAs. *See Doe v. Rumsfeld*, 341 F. Supp. 2d 1 (D.D.C. 2004) (relying on 10 U.S.C. § 1107); *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) (same); *see also* 70 Fed. Reg. at 44,660 (requiring DOD to tell vaccine recipients the following: "On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The *Court's injunction* means you have the right to refuse to take the vaccine without fear of retaliation." (emphasis added)); 70 Fed. Reg.

at 5454 (discussing litigation); *see also infra* note 15 (explaining that 10 U.S.C. § 1107(f) is inapplicable to EUAs).

B.

Section 564(e)(1)(A)(ii)(III) also raises a question about how to understand its cognate provision regarding the use of EUA products by the armed forces. As we noted above, in the same 2003 legislation that first created section 564, Congress also added the following provision to title 10 of the United States Code:

> In the case of the administration of [an EUA] product . . . to members of the armed forces, the condition described in section 564(e)(1)(A)(ii)(III) . . . and required under paragraph (1)(A) or (2)(A) of such section 564(e), designed to ensure that individuals are informed of an option to accept or refuse administration of a product, may be waived only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security.

10 U.S.C. § 1107a(a)(1).[15] On its own terms, this provision appears to be consistent with—and even to support—our reading of section 564, as it likewise describes the "option to accept or refuse" condition in purely informational terms. The language refers to the President's authority to

[15] Section 1107(f) of title 10—an earlier-enacted provision—contains a similar, but importantly different, waiver authority. Specifically, that provision authorizes the President, "[i]n the case of the administration of an [IND] or a drug unapproved for its applied use to a member of the armed forces in connection with the member's participation in a particular military operation," to waive "the prior consent requirement imposed under [21 U.S.C. § 355(i)(4)]." 10 U.S.C. § 1107(f)(1). That "prior consent requirement," which is imposed for purposes of the human clinical trials for which FDA authorizes "investigational" use of unapproved drugs, *see* 21 U.S.C. § 355(i)(4), does not apply to EUA products, which typically are more widely available, *see* FDCA § 564(k); EUA Guidance at 24 ("informed consent as generally required under FDA regulations is not required for administration or use of an EUA product" (footnote omitted)). Thus, the waiver provision in section 1107(f) is inapplicable to EUA products. *See* 10 U.S.C. § 1107(f)(2) (explaining that this waiver authority applies only in cases in which "prior consent for administration of a particular drug is required" because the Secretary of HHS determines that the drug "is subject to the [IND] requirements of [21 U.S.C. § 355(i)]"); *see also id.* § 1107(f)(4) (defining the relevant consent requirements as those in 21 U.S.C. § 355(i)).

waive a requirement to provide certain information, not to waive any right or affirmative "option" to refuse administration of the product itself.

On the other hand, the conference report on the legislation that created both section 564 of the FDCA and section 1107a of title 10 described the latter provision in the following way:

> [This provision] would authorize the President to waive *the right of service members to refuse administration of a product* if the President determines, in writing, that affording service members the right to refuse the product is not feasible, is contrary to the best interests of the members affected, or is not in the interests of national security.

H.R. Rep. No. 108-354, at 782 (2003) (Conf. Rep.) (emphasis added). This language indicates that the conferees may have believed that section 1107a concerns some "right" of members of the armed forces to refuse the use of EUA products. And that belief may help to explain why section 1107a allows only the President to exercise the waiver authority.

Consistent with this legislative history and the vesting of the waiver authority in the President, DOD informs us that it has understood section 1107a to mean that DOD may not require service members to take an EUA product that is subject to the condition regarding the option to refuse, unless the President exercises the waiver authority contained in section 1107a. *See* DOD Instruction 6200.02, § E3.4 (Feb. 27, 2008) ("In the event that an EUA granted by the Commissioner of Food and Drugs includes a condition that potential recipients *are provided an option* to refuse administration of the product, the President may . . . waive *the option* to refuse for administration of the medical product to members of the armed forces." (emphasis added)). Moreover, we understand that DOD's position reflects the concern that service members, unlike civilian employees, could face serious criminal penalties if they refused a superior officer's order to take an EUA product. *See* 10 U.S.C. § 890; *see also United States v. Kisala,* 64 M.J. 50 (C.A.A.F. 2006) (upholding a soldier's punishment for refusing to take a vaccine). In this way, service members do not have the same "option" to refuse to comply with a vaccination requirement as other members of the public.

As noted above, it does appear that certain members of Congress thought that section 1107a concerned a prohibition against requiring service members to take an EUA product—perhaps on the view that the

waiver authority in section 1107a paralleled the one in 10 U.S.C. § 1107(f), which does effectively prohibit the administration of an IND product in a clinical trial without first obtaining the individual's affirmative, informed *consent*. *See supra* note 15 (distinguishing these waiver authorities).[16] As explained, however, that intent or expectation is not realized in the text of section 564(e)(1)(A)(ii)(III), which section 1107a expressly cross-references. *Cf. Steinle v. City & Cty. of San Francisco*, 919 F.3d 1154, 1164 n.11 (9th Cir. 2019) ("[T]he plain and unambiguous statutory text simply does not accomplish what the Conference Report says it was designed to accomplish."); *Goldring v. Dist. of Columbia*, 416 F.3d 70, 75 (D.C. Cir. 2005) ("A sentence in a conference report cannot rewrite unambiguous statutory text[.]").[17] We therefore conclude that section 1107a does not change our interpretation of section 564 of the FDCA.

As for DOD's concern about service members who would lack a meaningful option to refuse EUA products because of the prospect of sanction, including possibly prosecution, we note that any difference between our view and the assumption reflected in the conference report should have limited practical significance. Given that FDA has imposed the "option to accept or refuse" condition for the COVID-19 vaccines by requiring

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[16] It is possible the conferees assumed that the new EUA legislation would, in effect, carry over from the earlier IND provision of the FDCA, *see supra* Part I.A and note 11, the condition that a covered product may not be administered to an individual without that person's express, informed consent—a condition that applies to the military when it undertakes the sort of clinical trial with an IND that 21 U.S.C. § 355(i) governs, *see supra* note 11. Congress did not include such a consent requirement in section 564, however, perhaps because EUA products are not limited, as INDs are, to use in human clinical trials, but are instead authorized for more widespread use in the case of a declared emergency. *See supra* Part I.A and notes 11 & 15.

[17] Moreover, the legislative history as a whole is not uniform on this point. The earlier House report, for instance, described the condition in purely informational terms. *See* H.R. Rep. No. 108-147, pt. 3, at 33 (2003) ("New section 564(k) [an earlier but similarly worded version of what became 10 U.S.C. § 1107a] pertains to members of the Armed Forces and, among other things, it specifies that the President may waive requirements designed to ensure that such members are *informed* of the option to accept or refuse administration of an emergency use product, upon certain findings[.]" (emphasis added)); *see also Milner v. Dep't of the Navy*, 562 U.S. 562, 574 (2011) (noting that "[l]egislative history, for those who take it into account, is meant to clear up ambiguity, not create it," and thus, "[w]hen presented, on the one hand, with clear statutory language and, on the other, with dueling committee reports, we must choose the language").

distribution of its Fact Sheet containing the "[i]t is your choice to receive or not receive" language, DOD is required to provide service members with the specified notification unless the President waives the condition pursuant to 10 U.S.C. § 1107a. And because DOD has informed us that it understandably does not want to convey inaccurate or confusing information to service members—that is, telling them that they have the "option" to refuse the COVID-19 vaccine if they effectively lack such an option because of a military order—DOD should seek a presidential waiver before it imposes a vaccination requirement.

III.

For the reasons set forth above, we conclude that section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs.

DAWN JOHNSEN
Acting Assistant Attorney General
Office of Legal Counsel

SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

AUG 09 2021

MEMORANDUM FOR ALL DEPARTMENT OF DEFENSE EMPLOYEES

SUBJECT: Message to the Force

As many of you know, President Biden asked me to consider how and when we might add the coronavirus disease 2019 (COVID-19) vaccines to the list of those required for all Service members. So, over the last week, I have consulted closely with the Chairman of the Joint Chiefs of Staff, the Secretaries of the Military Departments, the Service Chiefs, and medical professionals. I appreciate greatly the advice and counsel they provided.

Based on these consultations and on additional discussions with leaders of the White House COVID Task Force, I want you to know that I will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon the U.S. Food and Drug Administration (FDA) licensure, whichever comes first.

By way of expectation, public reporting suggests the Pfizer-BioNTech vaccine could achieve full FDA licensure early next month.

The intervening few weeks will be spent preparing for this transition. I have every confidence that Service leadership and your commanders will implement this new vaccination program with professionalism, skill, and compassion. We will have more to say about this as implementation plans are fully developed.

In the meantime, we will comply with the President's direction regarding additional restrictions and requirements for unvaccinated Federal personnel. Those requirements apply to those of you in uniform as well as our civilian and contractor personnel.

We will also be keeping a close eye on infection rates — which are on the rise now due to the Delta variant — and the impact these rates might have on our readiness. I will not hesitate to act sooner or recommend a different course to the President if I feel the need to do so.

To defend this Nation, we need a healthy and ready force. I strongly encourage all DoD military and civilian personnel — as well as contractor personnel — to get vaccinated now and for military Service members to not wait for the mandate.

All FDA-authorized COVID-19 vaccines are safe and highly effective. They will protect you and your family. They will protect your unit, your ship, and your co-workers. And they will ensure we remain the most lethal and ready force in the world.

Get the shot. Stay healthy. Stay ready.

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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

THE DIRECTOR

April 12, 2024

M-24-12

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Shalanda D. Young

SUBJECT: Updated Guidance Regarding COVID-19 Safe Federal Workplace: Agency Model Safety Principles and COVID-19 Workplace Safety Plans

The President has issued the Executive Order of April 12, 2024, on COVID-19 and Public Health Preparedness and Response (E.O. of April 12, 2024), which revoked E.O. 13991 of January 20, 2021, on Protecting the Federal Workforce and Requiring Mask Wearing. E.O. 13991 had established the Safer Federal Workforce Task Force (Task Force). The Administration has determined that the Task Force is no longer necessary as the country has transitioned from an emergency response to a longer-term response to COVID-19 and pandemic preparedness in general.

In addition, the Office of Pandemic Preparedness and Response Policy (OPPR), established under section 2104 of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), is playing a critical role in the Federal Government's pandemic preparedness efforts, including by providing advice, within the Executive Office of the President, on policy related to preparedness for, and response to, pandemic and biological threats that may impact national security.

In light of the issuance of the E.O. of April 12, 2024, this Memorandum revokes Office of Management and Budget (OMB) Memorandum M-21-15 of January 24, 2021, which had required Federal agencies to develop and maintain agency COVID-19 workplace safety plans in accordance with the Task Force's model safety principles. In addition, this Memorandum instructs agencies to take the following steps as a general management practice to support the ongoing and longer-term Federal efforts in maintaining a safe and healthy Federal workplace and ensuring future preparedness, consistent with the policy in the E.O. of April 12, 2024:

(1) Continue to maintain, update, and implement workplace safety plans. Agencies may refer to guidance from the Centers for Disease Control and Prevention (CDC), Occupational Safety and Health Administration (OSHA), and other agencies, as applicable.

(2) Notify OMB following any significant revision to their workforce safety plans.

The Task Force website will continue to be preserved but not updated, with a banner notification referencing the termination of the Task Force and preservation of the website's contents for archival purposes only.

Prior to termination, Task Force guidance included instruction on Federal employees' use of leave in connection with the COVID-19 emergency. Going forward, the Office of Personnel Management will assume the role of providing agencies with guidance on the use of leave in various circumstances related to COVID-19 and other public health emergencies.

Background

Pursuant to the now-revoked E.O. 13991, the Task Force provided ongoing guidance to heads of agencies on the operation of the Federal government, the safety of its employees, and the continuity of government functions during the Administration's response to the COVID-19 pandemic. This guidance was informed by best practices determined by the CDC and other public health experts. OMB Memorandum M-21-15 required that agencies form COVID-19 Coordination Teams to develop and maintain tailored agency COVID-19 workplace safety plans consistent with CDC guidelines and model safety principles from the Task Force that were included in the Memorandum. The Task Force and OMB worked with agencies to review, finalize, and, as needed, update such plans. Agencies completed and implemented those plans, responding to updated guidance and information from the CDC and the Task Force as conditions and recommendations evolved. For example, in August 2022, the Task Force issued implementation guidance that reflected the most significant updates to CDC guidance on COVID-19, and in September 2022, the Task Force issued updated model safety principles.

Agency Action

To facilitate ongoing and longer-term work in maintaining a safe and healthy Federal workplace and ensuring pandemic preparedness, and consistent with general management practice, Federal agencies are instructed to:

(1) **Continue to maintain and implement workplace safety plans.** Agencies should continue to maintain and implement workplace safety plans and associated policies and procedures and refer to guidance from the CDC and other Federal workplace safety agencies, including OSHA.

Agencies should anticipate that workplace safety plans could evolve over time to address broader pandemic preparedness or other workplace safety issues. Additionally, the CDC's routine public health information and guidance addresses the prevention of other circulating respiratory viruses, such as influenza and respiratory syncytial virus, in addition to COVID-19.[1]

[1] Centers for Disease Control and Prevention Respiratory Virus Guidance https://www.cdc.gov/respiratory-viruses/index.html

Agencies should continue to satisfy any applicable collective bargaining obligations as required regarding any changes to plans and should provide appropriate notice of relevant plan updates to their employees, employee representatives, and onsite contractors. To the extent collective bargaining agreements (CBAs) have codified COVID-19 safety requirements with more stringent safety standards than provided in CDC guidance or agency workplace safety plans, agencies are obligated to honor the CBAs and may seek to renegotiate these requirements when the CBA is subject to re-negotiation. If agencies have CBA provisions which require the agency to specifically follow or comply with Safer Federal Workforce Task Force guidance or E.O. 13991, agencies should review these provisions to determine whether they remain applicable and communicate, as appropriate, with employee representatives.

Agencies should continue to ensure that all employees, on-site contractors, and visitors to Federal workplaces are aware of workplace safety protocols, such as by updating their guidance on visitors, travel, testing, and vaccination, as well as relevant signage as needed.

(2) Notify OMB following any significant revision to their workforce safety plans. As a matter of management practice, agencies should notify OMB following any significant changes to their workplace safety plans.

The actions described in this Memorandum will continue to maintain appropriate consistency across agencies with respect to their processes for maintaining and updating workplace safety plans to address maintaining a safe and healthy Federal workplace and ensuring future preparedness.

June 10, 2021

M-21-25

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES

FROM: Shalanda D. Young
Acting Director
Office of Management and Budget

Kathleen McGettigan
Acting Director
Office of Personnel Management

Katy Kale
Acting Administrator
General Services Administration

SUBJECT: Integrating Planning for A Safe Increased Return of Federal Employees and Contractors to Physical Workplaces with Post-Reentry Personnel Policies and Work Environment

The Administration is committed to ensuring that the Federal Government is a model employer, with the health, safety, and physical and mental wellbeing of its workforce paramount. Significant progress is being made in our fight against the COVID-19 pandemic, with case counts dropping and vaccinations levels rising nationwide. Given that progress, the Administration is taking prudent steps to plan for an effective, orderly, and safe increased return of Federal employees and contractors to the physical workplace ("reentry"). Executive departments and agencies (agencies) must integrate their planning for reentry with their planning for post-reentry personnel policies and work environment. This memorandum provides agencies with guidance for agency planning processes.

I. Background

Over the past 15 months, Federal employees, like Americans nationwide, have demonstrated their resiliency time and again during the COVID-19 pandemic. Many thousands of Federal employees with responsibilities that could not be performed remotely have continued to undertake mission-critical duties at their workplaces and on the frontlines of the national response, day-in and day-out through the pandemic. They and their families have made sacrifices to continue to serve the American public. They have inspected our food and ensured food security for our most vulnerable neighbors, kept our airports safe, and delivered medical care to our veterans and communities. They also guided and oversaw the historic development of the COVID-19 vaccine and its widespread distribution, saving lives and allowing our economy to get back on track. We owe

them a debt of gratitude. We also recognize the efforts of Federal employees whose duties could be performed via telework, for their continued work on behalf of the American people. Federal employees who transitioned quickly to full-time or partial telework at the start of the pandemic were able to support the mission and day-to-day operations of their agencies, develop and implement policies, manage relief programs, and continue to deliver results for all Americans.

The President took action on his first day in office to protect the health and safety of Federal employees and contractors from COVID-19 through the issuance of Executive Order 13991, Protecting the Federal Workforce and Requiring Mask Wearing (January 20, 2021), which established the Safer Federal Workforce Task Force (Task Force) and directed agencies to require compliance with Centers for Disease Control and Prevention (CDC) guidelines with respect to public health measures. Subsequently, Office of Management and Budget (OMB) Memorandum M-21-15, COVID-19 Safe Federal Workplace: Agency Model Safety Principles (January 24, 2021), required that agencies form COVID-19 Coordination Teams to develop and maintain tailored agency COVID-19 workplace safety plans consistent with CDC guidelines and the model safety principles provided by M-21-15. Since that time, agencies have completed and implemented those plans, responding to updated guidance and information from the CDC and the Task Force as conditions change.

In addition, since March 2020, Federal employees and the agencies that employ them have adapted and embraced innovative ways of working to deliver on their missions. The Federal Government quickly went from 3 percent of employees teleworking every day to nearly 60 percent, as shown in the 2020 Office of Personnel Management (OPM) Federal Employee Viewpoint Survey (FEVS).[1] At the same time, those employees who needed to perform mission-critical, on-site work continued to fulfill their responsibilities in the physical workplace or in the field. This rapid shift to increased telework and remote work was made possible because of agency investments in information technology (IT) modernization, such as adoption of cloud-based solutions, as well as the broad and strategic application of personnel policies, including weather-and-safety leave, pandemic evacuation, telework, remote work, alternative work schedules, and leave flexibilities. Throughout these changes, agencies continued to deliver on their mission.

II. Update on Federal Government Operational Status

The Task Force continues to provide updates to agencies regarding COVID-19 workplace safety. This memorandum **rescinds OMB Memorandum M-20-23**, Aligning Federal Agency Operations with the National Guidelines for Opening Up America Again (April 20, 2020), and includes the following updates for agencies from the Task Force:

A. **Agencies' COVID-19 Workplace Safety Plans remain in effect and should be updated as needed to align with current guidance.** COVID-19 workplace safety plans remain in effect across Federal workplaces. Agencies should continue to update those plans and associated policies and procedures to align with current guidance from the Task Force and CDC, such as the recently updated CDC Interim Recommendations for Fully Vaccinated Individuals, as well as other relevant guidance from Federal workplace safety agencies,

[1] Governmentwide Management Report: Results from the 2020 OPM Federal Employee Viewpoint Survey: https://www.opm.gov/fevs/reports/governmentwide-reports/governmentwide-management-report/governmentwide-report/2020/2020-governmentwide-management-report.pdf

such as the Department of Labor's Occupational Health and Safety Administration (OSHA).

B. **Occupancy in Federal workplaces.** The occupancy requirements set forth in M-21-15 are no longer in effect, although other aspects of M-21-15 remain in effect pursuant to current CDC guidelines, as do agencies' COVID-19 workplace safety plans, as noted above, to ensure the safety of Federal employees. Agencies may establish occupancy limits for specific workplaces as a means of ensuring physical distancing between unvaccinated individuals. As set forth in Section IV(B)(4), prior to increasing the number of employees in the physical workplace, an agency must complete its phased plan for reentry and post-reentry, ensure it has an updated COVID-19 workplace safety plan pursuant to current CDC guidelines, satisfy any applicable collective bargaining obligations, and provide ample notice to any affected employees. An agency may, on a limited basis, increase the number of employees or contractors in the physical workplace prior to taking one of those steps where necessary to meet urgent, mission-critical needs—any such action must be approved by the head of the agency, in consultation with OMB and OPM.

C. **Open with maximum telework flexibilities.** The Federal Government's nationwide operating status remains at "Open with maximum telework flexibilities to all current telework eligible employees, pursuant to direction from agency heads." Further changes to the Government's operating status, consistent with the most recent guidance and principles set forth by the CDC, will continue to be communicated to agencies by the Safer Federal Workforce Task Force at SaferFederalWorkforce.gov and on OPM's Operating Status website.[2]

D. **Heating, ventilation, and air conditioning (HVAC) operations in GSA-controlled facilities.** Throughout the course of the pandemic, the General Services Administration (GSA) has implemented several protective measures aimed at reducing the risk and spread of COVID-19 in facilities under its jurisdiction, custody, or control. For HVAC operations, these measures include taking steps to increase ventilation and improve air filtration in accordance with CDC guidelines. Onsite agency personnel working in GSA-controlled facilities can contact their GSA Facility Manager for more information on the specific steps taken in the facility in which they are located.

E. **Exceptions process.** As a reminder, at any time, if there are operational needs related to the completion of agency mission-critical activities, agencies may pursue an exception from select model safety principles set forth by M-21-15, and as amended by Task Force guidance and this memorandum. The Task Force will review these exception requests to ensure that the agency's proposed mitigation measures protect the health and safety of the Federal workforce engaged in essential onsite work. Exception requests should be approved by the head of the agency and emailed to SaferFederalWorkforce@gsa.gov, using the form previously provided to agency staff representatives to the President's Management Council. Agencies may also request a copy of the exceptions request form by emailing SaferFederalWorkforce@gsa.gov.

[2] Current Status (opm.gov): https://www.opm.gov/policy-data-oversight/snow-dismissal-procedures/current-status/

III. Planning and Preparing for a Safe Increased Return of Federal Employees and Contractors to Physical Workplaces, as well as the Post-Reentry Work Environment

The Task Force—in collaboration with OMB, OPM, and GSA—has charged **all agencies to complete their planning for reentry by July 19, 2021**—how and when to return an increased number of employees and contractors, as appropriate, in-person to the Federal workplace—as well as their intended post-reentry personnel policies and work environment. This agency planning includes two main components:

A. A phased plan for reentry and post-reentry

Agencies will develop and provide to OMB a draft of their proposed approaches to post-reentry personnel policies and work environment by June 18, 2021. Agencies included in the Chief Financial Officers Act of 1990 (P.L. 101-576) (CFO Act agencies) should develop a draft schedule for phased reentry of personnel, to be provided to OMB by July 9, 2021. Combined, these two documents will constitute the agency's phased plan for reentry and post-reentry. Agencies should work with OMB to finalize their phased plans for reentry and post-reentry by no later than July 19, 2021, informed by this and other guidance from the Task Force, OMB, OPM, and GSA. Note: while non-CFO Act agencies are not required to submit to OMB a draft reentry schedule by July 9, 2021, they also must finalize their phased plan for reentry and post-reentry by no later than July 19.

As described further below, this planning deadline does not reflect agencies' satisfaction of labor relations requirements, formal notifications or announcements to employees, or implementation of the plan, which generally will occur after the agency develops its phased plan.

The planning documents described above are not intended for publication or release by the agency. In addition, these planning documents do not need to be provided at the level of each division, office, or team across the agency and need not include specific policies, procedures, or detailed timelines. Rather, these plans should be a summary of the high-level guidelines that the agency will put in place to inform decisions within the agency and its sub-organizations. As discussed further below, agencies are expected to develop policy guidelines that provide guardrails for decision making across divisions, offices, and teams. Most decisions about application of those policy guidelines should be delegated to the lowest possible levels in the organization, to provide maximum flexibility for defining work requirements to meet mission and workforce needs. OMB expects that agencies will develop documentation (including policies), communication materials, and other materials to share the details of agency plans for reentry and post-reentry across the agency, both in a general manner and also with tailored information for supervisors, employees, and employee representatives, specific to those individuals' divisions, offices, and teams.

Agency plans for reentry and post-reentry should be informed by lessons learned during the past 15 months. The agency's eventual post-pandemic operating state may differ in significant ways from the agency's pre-pandemic operating state.

B. An update of the agency's COVID-19 workplace safety plan

Prior to implementation of their phased plan for reentry and post-reentry, agencies should work with the Task Force to update their COVID-19 workplace safety plan pursuant to current CDC guidelines. Non-CFO Act agencies are not required to submit a draft updated COVID-19 workplace safety plan as part of this process.

Once reviewed by the Task Force and updated, and following satisfaction of any collective bargaining obligations, the agency should communicate its updated COVID-19 workplace safety plan to its employees, their representatives, and onsite contractors, and publish it on the agency's website, prior to the agency initiating an increased return of employees and contractors to physical workplaces. As part of this planning effort, OMB, in coordination with the Task Force, will update the model safety principles in M-21-15, consistent with the latest CDC guidance. The Task Force will provide agencies with a checklist to help guide agencies' required updates to their respective COVID-19 workplace safety plans.

Regarding employee and contractor vaccination status: As recently shared with agencies by the Task Force, the Administration strongly encourages all Americans, including Federal employees and contractors, to be vaccinated. Employees should receive paid time off to be vaccinated and to deal with any side effects. At present, COVID-19 vaccination should generally not be a pre-condition for employees or contractors at agencies to work in-person in Federal buildings, on Federal lands, and in other settings as required by their job duties. Federal employees and contractors may voluntarily share information about their vaccination status, but agencies should not require Federal employees or contractors to disclose such information. Responding to agency inquiries should be voluntary, and agencies should comply with any applicable laws, including requirements under the Privacy Act and the Paperwork Reduction Act, and any applicable collective bargaining obligations. When an employee or contractor voluntarily discloses that they are unvaccinated or declines to provide vaccination information, agencies should use that information to implement CDC-recommended mitigation measures, including masking and physical distancing.

IV. Values-Informed Planning for Post-Reentry Personnel Policies and Work Environment

Agency planning is already in progress for post-reentry personnel policies and work environment through the President's Management Council (PMC), as part of a process led jointly by OMB, GSA, and OPM.

This guidance has been informed by input from the PMC Working Group on Reentry and the Future of Work, which is the primary interagency convening body for agency feedback and questions on: (1) determining what post-reentry Federal personnel policies and the work environment will look like after more employees and contractors safely return to the physical workplace; and (2) connecting post-reentry workforce planning to long-term trends to shape the future of work in the Federal context. The working group includes representatives from OMB, OPM, GSA, the 24 CFO Act agencies, and the interagency management councils, including the Chief Human Capital Officers Council, the Chief Information Officers Council, the Chief

Financial Officers Council, the Federal Real Property Council, and the Chief Acquisition Officers Council.

Topics of consideration by the Working Group include, for example:

- Integrating learning from employee and supervisor experiences;
- Ensuring consistent approaches across agencies to phased timelines for reentry of employees returning to the physical workplace that account for labor relations obligations and provision of ample notice for affected employees;
- Addressing Government-wide telework and remote work policies, as well as flexible work schedules, pay, leave, performance management, and other personnel policies;
- Training and supporting employees and supervisors; and
- Considering effects on: workspaces and Federal real property; technology and information technology (IT) needs; onsite contractors; and local communities.

A. Values-Informed Planning

OMB, OPM, and GSA expect that agency decisions in these areas will be equitable and grounded in values that empower, respect, and galvanize the Federal workforce, while reflecting and emphasizing trust and accountability for the American people they serve. In making decisions regarding post-reentry personnel policies and the work environment, agencies should also consider broader workforce and workplace trends and the need for the Federal Government to be competitive for top talent as employers in the broader labor market. Agency leaders can leverage issues such as telework, remote work, and flexible work schedules as tools in their broader strategies for talent recruitment and retention, and for advancing diversity, equity, inclusion, and accessibility in the Federal workforce. These values-informed planning activities will help to ensure that the Administration:

- Builds a collaborative and flexible workplace environment that embraces the wellbeing of its employees;
- Reinforces its commitment to the Federal workforce and its role as a model employer;
- Achieves appropriate consistency across agencies, while providing agencies and sub-organizations sufficient flexibility on workforce and workplace decisions;
- Responds to available data on the Federal workforce, as well as data on the U.S. workforce;
- Assesses and evaluates what types of personnel policies and work environments are most effective for delivery of the agency's mission;
- Attracts and retains talent in the context of changing workforce trends; and
- Enhances engagement and morale of Federal employees, while delivering against agency missions effectively, equitably, and efficiently.

B. Planning Guidelines for Agency Post-Reentry Personnel Policies and Work Environment

Below are expectations and guidelines to help inform agency planning and decision-making related to post-reentry personnel policies and the work environment. Additional guidance from OPM related to telework, remote work, hours of work, performance management, and labor relations is included in the attached Appendix 1. Considerations for agencies from GSA on workplace planning are included in the attached Appendix 2.

1. Government-Wide Personnel Policy Guidelines to Promote Flexibility

Agencies will need to balance priorities in making decisions related to post-reentry personnel policies and the work environment. Overall, agencies' decisions must be guided by how they can most effectively achieve their respective missions. As shown during the pandemic, agencies can, where appropriate, deploy personnel policies such as telework, remote work, and flexible work schedules effectively and efficiently as strategic management tools for attracting, retaining, and engaging talent to advance agency missions, including in the context of changes in workplaces nationwide as a result of the pandemic and in response to long-term workforce trends.

Consistent with the Administration's commitment to protect, support, and empower the Federal workforce, OMB, OPM, and GSA anticipate that many agencies will leverage such personnel policies and associated flexibilities in their post-reentry work environments more expansively than was the case prior to the pandemic, informed by consultation with agency leadership, supervisors, employees, and employee representatives, as well as by data about the Federal workforce and the U.S. workforce at large. The Government-wide policy guidelines provided herein are intended to foster consistency across agencies, while encouraging flexibility among agencies to meet unique mission and workforce needs.

2. Making Agile Personnel Policy Decisions with Supervisor and Employee Support

OMB, OPM, and GSA anticipate that agencies (and their bureaus/components) will identify personnel policy guidelines that provide guardrails for decision making across divisions, offices, and teams, but that most decisions about application of those policy guidelines will be delegated to the lowest appropriate levels in the organization to provide maximum flexibility for defining work requirements to meet mission and workforce needs.

To facilitate consistent and equitable application of such guidelines across the agency's workforce, agencies should provide support for supervisors and employees, including, for example, health, safety, facilities, and space considerations, reentry toolkits, checklists, and training for supervisors on managing hybrid and remote teams and for employees on reentry planning and performance expectations and obligations in a hybrid or remote work environment, as appropriate.

As agencies introduce, pilot, evaluate, and scale new and different personnel policies in the post-reentry work environment, they should regularly solicit feedback from agency leadership, supervisors, employees (including not only employees who have been able to telework, but also "front-line" and other employees who already have been working onsite or in the field), employee representatives and unions, and other stakeholders, such as representatives of local communities near Federal workplaces and other stakeholders who require frequent interactions with the agency, to inform any future changes.

Agencies and organizations should rely on evidence when making their decisions, including by:

- Seeking and considering data and information regarding the impact of personnel policies and procedures on employee engagement, mission delivery, and outcomes;
- Establishing frequent feedback mechanisms, such as pulse surveys; and
- Leveraging evaluation and decision-making processes that support regular, data-driven updates to policies and procedures as the needs of the people agencies serve and of the Federal workforce continue to evolve.

The Wayback Machine - https://web.archive.org/web/20211204024111/https://www.cdc.gov/coronavirus/2019-ncov/testing/self-...

Self-Testing

Updated Nov. 4, 2021

Summary of Recent Changes

Updates as of November 4, 2021

- Self-testing videos are now available to assist with how to use and interpret self-tests.
- Removed recommendation to report test results to healthcare providers or health departments.
- Added guidance about seeking assistance from a healthcare provider if the test result seems incorrect.

Key Points

- Self-tests are performed by a person at home or anywhere.
- All instructions for performing the test must be followed.
- Self-tests can be used by anyone who is symptomatic regardless of their vaccination status.
- Unvaccinated people without COVID-19 symptoms can also use self-tests, especially if they were potentially exposed to someone with COVID-19.
- If a person tests positive, they should isolate and inform any close contacts.

COVID-19 Viral Testing Tool

A tool to help you understand COVID-19 testing options.

Get Started About the Tool

Video Resources

How To Use a Self Test

Overview

Note: If your COVID-19 test is positive, tell a healthcare provider about your positive result and stay in contact with them during your illness. To avoid spreading the virus to others, follow CDC's guidance for isolation. As much as possible, stay in a specific room and away from other people and pets in your home or place of residence. Tell your close contacts that they may have been exposed to COVID-19.



Testing is critically important to help reduce the spread of COVID-19. If you have symptoms or have had a known exposure to someone with suspected or confirmed COVID-19, you should be tested regardless of your vaccination status. If you have recovered from COVID-19 within the past 90 days, you should consult with a healthcare provider regarding being tested again for new or worsening symptoms. Quarantine if you have been in close contact (within 6 feet of someone for a cumulative total of 15 minutes or more over a 24-hour period) with someone who has COVID-19 unless you have been fully vaccinated.

People who are fully vaccinated do not need to quarantine after contact with someone who had COVID-19 unless they have or develop symptoms. A fully vaccinated asymptomatic person should get tested 5–7 days following a known exposure to someone with suspected or confirmed COVID-19 and wear a mask in public indoor settings for 14 days after exposure or until receiving a negative test result within that window. Although only a small proportion of fully vaccinated people become infected with COVID-19, any fully vaccinated person who experiences symptoms consistent with COVID-19 should isolate themselves from others, be clinically evaluated for COVID-19, and test for the virus that causes COVID-19.

Fully vaccinated individuals should follow CDC's recommendations for testing.

If you need to be tested for COVID-19, you can consider using either a **self-collection kit** or a **self-test** that can be performed at home or anywhere else. Sometimes a self-test is also called a "home test" or an "at-home test." FDA provides information on which self-tests are authorized for use.

These self-collection kits and tests are available in pharmacies and retail stores. Some self-collection kits and self-tests require a prescription. At present, self-collection kits and self-tests are used for the detection of current infection.

Read the complete manufacturer's instructions before using the test. Talk to a healthcare provider if you have questions about the test or your results.

Types of Specimens

- Some tests require a **nasal specimen** that can be collected using an anterior nasal swab or a nasal mid-turbinate swab (see the Print Resources section below).
- Other tests require a **saliva specimen**.

Prepare to Collect a Specimen

- Wash your hands with soap.

The Wayback Machine - https://web.archive.org/web/20211221023604/https://www.cdc.gov/coronavirus/2019-ncov/testing/self-...

Self-Testing

Updated Dec. 6, 2021

Summary of Recent Changes

Updates as of December 6, 2021

- Added information on when and why to use a self-test. Self-testing is one of several risk-reduction strategies to reduce the chances of COVID-19 transmission. They may be used regardless of vaccination or symptom status.

Previous updates

Key Points

- COVID-19 self-tests (also referred to as home tests or over-the-counter (OTC) tests) are one of many risk-reduction measures, along with vaccination, masking, and physical distancing, that protect you and others by reducing the chances of spreading SARS-CoV-2, the virus that causes COVID-19.
- Self-tests can be taken at home or anywhere, are easy to use, and produce rapid results.
- You can use self-tests, regardless of vaccination status, or whether or not you have symptoms.
- Follow all of the manufacturer's instructions for performing the test.
- If you test positive, you should isolate and inform your healthcare provider, as well as any close contacts.
- Consider using a self-test before joining indoor gatherings with others who are not in your household.
- A positive self-test result means that the test detected the virus, and you are very likely to have an infection and should stay home or isolate for 10 days, wear a mask if you could have contact with others, and avoid indoor gatherings to reduce the risk of spreading disease to someone else.
- A negative self-test result means that the test did not detect the virus and you may not have an infection, but it does not rule out infection. Repeating the test within a few days, with at least 24 hours between tests, will increase the confidence that you are not infected.

CDC Centers for Disease Control and Prevention

COVID-19

To maximize protection from the Delta variant and prevent possibly spreading it to others, get vaccinated as soon as you can and wear a mask indoors in public if you are in an area of substantial or high transmission.

Interim Guidance for SARS-CoV-2 Testing in Non-Healthcare Workplaces

Updated Mar. 17, 2021

Summary of Recent Changes

Updates as of March 17, 2021

- Added description of nucleic acid amplification tests (NAATs) and antigen tests as types of viral tests to align with the Overview of Testing for SARS-CoV-2
- Added considerations on incorporating testing of asymptomatic individuals without known or suspected exposure to SARS-CoV-2 (screening testing) in select workplace settings as part of a workplace COVID-19 prevention and control plan
- Updated considerations on frequency of testing

View Previous Updates

Key Points

- Workplace-based testing for SARS-CoV-2, the virus that causes COVID-19, could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission. The purpose of this guidance is to provide employers with considerations for incorporating testing for SARS-CoV-2 into a workplace COVID-19 preparedness, response, and control plan in select non-healthcare workplaces.
- This guidance includes descriptions of different types of SARS-CoV-2 tests; scenarios where SARS-CoV-2 testing may be used; considerations for screening testing (testing asymptomatic workers with no known or suspected exposure to SARS-CoV-2); and use of antigen tests for serial screening testing, including in high-density critical infrastructure workplaces.
- Screening testing could be effective in helping to prevent transmission for select workplace settings.
- These interim considerations on SARS-CoV-2 testing strategies for select non-healthcare workplaces during the COVID-19 pandemic are based on what is currently known about the transmission and severity of COVID-19 and is subject to change as additional information becomes available.

Note: This document provides guidance on the appropriate use of testing and does not dictate the determination of payment decisions or insurance coverage of such testing, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.

Introduction

The purpose of this document is to provide employers with strategies for consideration of incorporating testing for SARS-CoV-2, the virus that causes COVID-19, into workplace preparedness, response, and control plans in select non-healthcare workplaces. For workplaces with healthcare personnel, including those that work in nursing homes, please refer to Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2 and Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel.

Employers are encouraged to collaborate with state, territorial, tribal and local health officials to determine whether and how to implement the following testing strategies and which one(s) would be most appropriate for their circumstances. These considerations are meant to supplement, not replace, any federal, state, local, territorial, or tribal health and safety laws, rules, and regulations with which workplaces must comply. These strategies should be carried out in a manner consistent with existing laws and regulations, including laws protecting employee privacy and confidentiality. They should also be carried out consistent with Equal Employment Opportunity Commission (EEOC) guidance regarding permissible testing policies and procedures. Employers paying for testing of employees should put procedures in place for rapid notification of results and establish appropriate measures based on testing results, including instructions regarding self-isolation and restrictions on workplace access.

Considerations when testing

SARS-CoV-2 testing may be incorporated as part of a comprehensive approach to reducing transmission in non-healthcare workplaces. Symptom screening, testing, and contact tracing are strategies to identify workers infected with SARS-CoV-2, the virus that causes COVID-19, so that actions can be taken to slow and stop the spread of the virus.

COVID-19 vaccine is currently available in limited doses; therefore, CDC's Advisory Committee on Immunization Practices (ACIP) described recommendations for prioritization during the early phases of the vaccination program. As vaccine supply increases and additional priority groups receive vaccine, CDC's priorities for SARS-CoV-2 testing will change and the guidance will be updated. For guidance on quarantine and testing of fully vaccinated people, please visit Interim Public Health Recommendations for Fully Vaccinated People.

Employees undergoing testing should receive clear information on

- the manufacturer and name of the test, the type of test, the purpose of the test, the performance specifications of the test, any limitations associated with the test, who will pay for the test, how the test will be performed, how and when they will receive test results, and;
- how to understand what the results mean, actions associated with negative or positive results, the difference between testing for workplace screening versus for medical diagnosis, who will receive the results, how the results may be used, and any consequences for declining to be tested.

Individuals tested are required to receive patient fact sheets as part of the test's emergency use authorization (EUA).

According to the Americans with Disabilities Act (ADA), when employers implement any mandatory testing of employees, it must be "job related and consistent with business necessity." In the context of the COVID-19 pandemic, the U.S. EEOC notes that testing to determine if an employee has SARS-CoV-2 infection with an "accurate and reliable test" is permissible as a condition to enter the workplace because an employee with the virus will "pose a direct threat to the health of others." EEOC notes that testing administered by employers that is consistent with current CDC guidance will meet the ADA's business necessity standard. However, workplace-based testing should not be conducted without the employee's consent. Employers who mandate workplace testing for SARS-CoV-2 infection should discuss further with employees who do not consent to testing and consider providing alternatives as feasible and appropriate such as reassignment to tasks that can be performed via telework.

The Occupational Safety and Health Administration has issued interim guidance for enforcing the requirements of 29 CFR Part 1904 with respect to the recording of occupational illnesses, specifically cases of COVID-19. Under OSHA's recordkeeping requirements, COVID-19 is a recordable illness, and thus employers are responsible for recording cases of COVID-19, if the case meets certain requirements. Employers are encouraged to frequently check OSHA's webpage at www.osha.gov/coronavirus for updates.

Test types

Viral tests

Viral tests authorized by the Food and Drug Administration (FDA) are used to **diagnose infection** with SARS-CoV-2, the virus that causes COVID-19. Viral tests evaluate whether the virus is present in respiratory or other specimens. Results from these tests help public health officials identify and isolate people who are infected to minimize SARS-CoV-2 transmission. See FDA's list of In Vitro Diagnostics Emergency Use Authorizations for more information about the performance of specific authorized tests.

- Nucleic acid amplification tests (NAATs), such as real-time reverse transcription-polymerase chain reaction (RT-PCR), detect viral ribonucleic acid (RNA) and indicate a current infection or a recent infection with prolonged viral RNA detection but without direct evidence for virus capable of replicating or of being transmitted to others. NAATs are high-sensitivity, high-specificity tests for diagnosing SARS-CoV-2 infection. Most NAATs need to be processed in a laboratory with variable time to results (~1–2 days), but some NAATs are point-of-care tests with results available in about 15–45 minutes.
- Antigen tests detect the presence of a specific viral antigen. Most can be processed at the point of care with results available in about 15–30 minutes. Antigen tests generally have similar specificity but are less sensitive than NAATs. Depending on the pre-test probability, antigen test results may need confirmation with a NAAT (e.g., a negative test in persons with symptoms or a positive test in persons without symptoms). Use of the Antigen Testing Algorithm [147 KB, 1 page] is **recommended** to determine when confirmatory testing is needed.

Antibody tests

Antibody (or serology) tests are used to detect previous infection with SARS-CoV-2 and can aid in the diagnosis of Multisystem Inflammatory Syndrome in Children (MIS-C) and in adults (MIS-A). CDC does not recommend using antibody testing to diagnose current infection. Depending on the time when someone was infected and the timing of the test, the test might not detect antibodies in someone with a current infection. In addition, it is not currently known whether a positive antibody test result indicates immunity against SARS-CoV-2; therefore, at this time, antibody tests should not be used to determine if an individual is immune against reinfection. Antibody testing is being used for public health surveillance and epidemiologic purposes. Because antibody tests can have different targets on the virus, specific tests might be needed to assess for antibodies originating from past infection versus those from vaccination. For more information about COVID-19 vaccines and antibody test results, refer to Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.

For more information, please refer to Overview of Testing for SARS-CoV-2.

Overview of testing scenarios

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has recent known or suspected exposure to SARS-CoV-2.

Examples of diagnostic testing include:

- Testing people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19
- Testing people who attended an event where another attendee was later confirmed to have COVID-19

Screening tests are intended to identify infected people who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that measures can be taken to prevent

further transmission.

Examples of screening testing include:

- Testing employees in a workplace setting
- Testing students, faculty, and staff in a school or university setting
- Testing a person before or after travel
- Testing at home for someone who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Choosing a test

When choosing which test to use, it is important to understand the purpose of the testing (e.g., diagnostic, screening), analytic performance of the test within the context of the level of community transmission, need for rapid results, and other considerations. Table 1 summarizes some characteristics of NAATs and antigen tests to consider. Most antigen tests that have received EUA from FDA are authorized for testing symptomatic persons within the first 5, 7, 12, or 14 days of symptom onset. Given the risk of transmission of SARS-CoV-2 from asymptomatic and presymptomatic persons with SARS-CoV-2 infection, use of antigen tests in asymptomatic and presymptomatic persons can be considered. FDA has provided a list of FAQ for healthcare providers who are using diagnostic tests in screening asymptomatic individuals , and the Centers for Medicare & Medicaid Services will temporarily exercise enforcement discretion [40 KB, 1 Page] to enable the use of antigen tests in asymptomatic individuals for the duration of the COVID-19 public health emergency under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Laboratories that perform screening or diagnostic testing for SARS-CoV-2 must have a CLIA certificate and meet regulatory requirements. Tests that have received an EUA from FDA for point of care (POC) use can be performed with a CLIA certificate of waiver.

Table 1. NAAT and Antigen Test Differences to Consider When Planning for Diagnostic or Screening Use

	NAATs	Antigen Tests
Intended Use	Detect *current* infection	Detect *current* infection
Analyte Detected	Viral Ribonucleic Acid (RNA)	Viral Antigens
Specimen Type(s)	Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva	Nasal, Nasopharyngeal
Sensitivity	Varies by test, but generally high for laboratory-based tests and moderate-high for point-of-care (POC) tests	Varies depending on the course of infection, but generally moderate-to-high at times of peak viral load*

Specificity		
High		
High		
Test Complexity		
Varies by Test		
Relatively Easy to Use		
Authorized for Use at the Point-of-Care		
Most are not, some are		
Most are, some are not		
Turnaround Time		
Most 1-3 days. Some could be rapid in 15 minutes		
Ranges from 15 minutes to 30 minutes		
Cost/Test^		
Moderate (~$75-$100/test)		
Low (~$5-$50/test)		
Advantages		
Most sensitive test method available		
Short turnaround time for NAAT POC tests, but few available		
Usually does not need to be repeated to confirm results		
Short turnaround time (approximately 15 minutes)+		
When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission in the community, workplace, etc.		
Comparable performance to NAATs in symptomatic persons and/or if culturable virus present, when the person is presumed to be infectious		
Disadvantages		
Longer turnaround time for lab-based tests (1–3 days)		
Higher cost per test		
A positive NAAT diagnostic test should not be repeated within 90 days, because people may continue to have detectable RNA after risk of transmission has passed		
May need confirmatory testing		
Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people		

**The decreased sensitivity of antigen tests might be offset if the POC antigen tests are repeated more frequently (i.e., serial testing at least weekly).
^ Costs for: NAATs , Antibody tests
+Refers to point-of-care antigen tests only.

Considerations for testing in different scenarios

Diagnostic testing

Testing persons with signs or symptoms consistent with COVID-19

Employers may consider conducting daily in-person or virtual health checks (e.g., symptom and temperature screening) to identify employees with signs or symptoms consistent with COVID-19 before they enter a facility, in accordance with CDC's Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19). Employers should follow guidance from the EEOC regarding confidentiality of medical records from health checks.

Vaccinated and unvaccinated workers with COVID-19 symptoms should be immediately separated from other employees, customers, and visitors, and sent home or to a healthcare facility, depending on how severe their symptoms are, and follow CDC guidance for caring for oneself. To prevent stigma and discrimination in the workplace, make employee health screenings as private as possible. CDC recommends that anyone with signs or symptoms of COVID-19 be tested and follow the advice of their healthcare provider. Waiting for test results prior to returning to work is recommended to keep potentially infected workers out of the workplace.

Employers are encouraged to implement flexible sick leave and supportive policies and practices as part of a comprehensive approach to prevent and reduce transmission among employees.

Positive test results using a viral test (NAAT or antigen) in persons with signs or symptoms consistent with COVID-19 indicate that the person has COVID-19. A negative antigen test in persons with signs or symptoms of COVID-19 should be confirmed by a laboratory-based NAAT, a more sensitive test. Results from NAATs are considered the definitive result when there is a discrepancy between the antigen and NAAT test. For more information, see the Antigen Test Algorithm [458 KB, 1 Page]. Positive test results should be interpreted to indicate that a person has COVID-19 and should not come to work and should isolate at home. Decisions to discontinue isolation for workers with COVID-19 and allow them to return to the workplace may follow either a symptom-based, time-based, or a test-based strategy (see Testing to determine resolution of infection below).

Testing asymptomatic persons with recent known or suspected exposure to SARS-CoV-2

Case investigation is typically initiated when a health department receives a report from a laboratory or testing site of a positive SARS-CoV-2 viral test result, or a report from a healthcare provider of a patient with a confirmed or probable diagnosis of COVID-19 .

In general, fully vaccinated workers with no COVID-like symptoms do not need to quarantine or be tested following an exposure to someone with suspected or confirmed COVID-19. However, those who work in congregate settings or other high-density workplaces (e.g., meat and poultry processing and manufacturing plants) should be tested after an exposure; however, they do not need to quarantine. For more guidance on quarantine and testing of fully vaccinated people, please visit Interim Public Health Recommendations for Fully Vaccinated People.

Viral testing is recommended for all unvaccinated close contacts (people who have been within 6 feet for a combined total of 15 minutes or more during a 24-hour period) of persons with COVID-19. Because of the potential for asymptomatic and pre-symptomatic transmission of SARS-CoV-2, it is important that unvaccinated individuals exposed to people with known or suspected COVID-19 be quickly identified and quarantined. Viral testing with NAATs or antigen tests can detect if these individuals are currently infected. The health department may ask the employer for assistance in identifying close contacts of the worker. Employers are encouraged to work with public health departments investigating cases of COVID-19 and tracing contacts to help reduce the spread of SARS-CoV-2 in their workplaces and communities.

Because there may be a delay between the time a person is exposed to the virus and the time that virus can be detected by testing, early testing after exposure at a single time point may miss many infections. Testing that is repeated at different points in time, also referred to as serial testing, is more likely to detect infection among close contacts of a COVID-19 case than testing done at a single point in time. Viral testing is recommended for close contacts of persons with COVID-19 who should be tested immediately after being identified, and if negative, tested again in 5–7 days after last exposure or

immediately if symptoms develop during quarantine.

While CDC continues to recommend a 14-day quarantine for unvaccinated individuals who are close contacts of a person with COVID-19, viral testing may also be used as part of an option to shorten the quarantine period. Local public health authorities determine and establish the quarantine options for their jurisdictions. Shortening quarantine may increase willingness to adhere to public health recommendations. However, shortened quarantines may be less effective in preventing transmission of COVID-19 than the currently recommended 14-day quarantine. In jurisdictions with shortened quarantine options, workplaces with higher risk of SARS-CoV-2 introduction or transmission, or with potential for greater negative impact if employees become infected SARS-CoV-2 (see Types of workplaces below), can consider restricting workers from entering the workplace until 14 days after their exposure.

Testing may also be considered for unvaccinated persons who might have been in close contact with persons diagnosed with COVID-19 in collaboration with the local health department if resources permit. A risk-based approach to testing possible contacts of a person with confirmed COVID-19 may be applied. Such an approach should take into consideration the likelihood of exposure, which is affected by the characteristics of the workplace and the results of contact investigations. In some settings, expanded screening testing (i.e., testing beyond individually identified close contacts to those who are possible close contacts), such as targeting workers who worked in the same area and during the same shift, may be considered as part of a strategy to control the transmission of SARS-CoV-2 in the workplace. High-risk settings that have demonstrated potential for rapid and widespread dissemination of SARS-CoV-2 include:

- High-density critical infrastructure workplaces, where workers are in the workplace for long periods (e.g., for 8–12 hours per shift) and have prolonged close contact with coworkers
- Workplaces where employees live in congregate settings (e.g., fishing vessels, offshore oil platforms, farmworker housing, or wildland firefighter camps)
- Workplaces with populations at risk for severe illness if they are infected, such as homeless shelters and workplaces with older workers

After a case of COVID-19 has been identified in a high-density critical infrastructure workplace, where workers are in prolonged close contact, NAAT or antigen testing can be used to diagnose infection in workers with known or suspected exposure to SARS-CoV-2. Employers are encouraged to consult with state, local, territorial, and tribal health departments to help inform decision-making about expanded screening testing.

If employees are tested after close contact or suspected close contact with someone who has a confirmed or probable diagnosis of COVID-19, care should be taken to inform these employees of their possible exposure to SARS-CoV-2 in the workplace while maintaining confidentiality of the individual with COVID-19, as required by the ADA and consistent with EEOC guidance regarding What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws .

Testing to determine resolution of infection

The decision to end isolation and return to the workplace for employees with suspected or confirmed SARS-CoV-2 infection should be made in the context of clinical and local circumstances. NAATs have detected SARS-CoV-2 RNA in some recovered people's respiratory specimens for up to 3 months after illness onset but without direct evidence that virus that can replicate or cause disease. Consequently, evidence supports a time-based and symptom-based strategy to determine when to discontinue isolation or other precautions rather than a test-based strategy. For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious disease experts. For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the symptom-based strategy.

Under the ADA, employers are permitted to require a healthcare provider's note to verify that employees are healthy and able to return to work. However, as a practical matter, employers should be aware that healthcare provider offices and medical facilities may be extremely busy during periods when community COVID-19 indicators are in the moderate to high categorizations (Table 2) and may not be able to provide such documentation in a timely manner. In such cases, employers should consider not requiring a healthcare provider's note for employees who are sick to validate their illness, qualify for sick leave, or to return to work. Most people with COVID-19 have mild illness, can recover at home without medical care, and can follow CDC recommendations to determine when to discontinue isolation and return to the workplace.

Screening testing

Testing asymptomatic persons without known or suspected exposure to SARS-CoV-2 for early identification, isolation, and disease prevention

When to consider screening testing

Screening testing of asymptomatic workers without known or suspected exposure to SARS-CoV-2 in select non-healthcare settings may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with community COVID-19 indicators in the moderate to high categorizations (Table 2, Table 3). Screening testing can be used in addition to symptom and temperature checks, which will miss asymptomatic or presymptomatic contagious workers. Persons with asymptomatic or presymptomatic SARS-CoV-2 infection are significant contributors to SARS-CoV-2 transmission.

In general, fully vaccinated workers should continue to follow employer guidance on screening testing. Please see Interim Public Health Recommendations for Fully Vaccinated People for more information.

Types of workplaces

Workplace settings for which screening testing of workers should be considered include:

- Workplaces at increased risk of introduction of SARS-CoV-2 (e.g., workplaces where workers are in close contact with the public, such as restaurants or salons, or workplaces in communities with moderate to high transmission)
- Workplaces where there is a higher risk of SARS-CoV-2 transmission (e.g., workplaces where physical distancing is difficult and workers might be in close contact, such as manufacturing or food processing plants, or workplaces that provide congregate housing for employees such as fishing vessels, offshore oil platforms, farmworker housing or wildland firefighter camps)
- Workplaces where SARS-CoV-2 infection among employees will lead to greater negative impact, such as
  - Workplaces in remote settings where medical evaluation or treatment may be delayed
  - Workplaces where continuity of operations is a high priority (e.g.,critical infrastructure sectors)
  - Workplaces with a high proportion of employees at increased risk for severe illness

Frequency of screening testing

Approaches may include initial testing of all workers before entering a workplace, periodic testing of workers at regular intervals, targeted testing of new workers or those returning from a prolonged absence (such as medical leave or furlough), or some combination of approaches. Given the incubation period for COVID-19 (up to 14 days), CDC recommends conducting screening testing at least weekly. Employers may find the following factors helpful to consider when determining the interval for periodic testing:

- The availability of testing, turnaround time, and cost
- The latency time period between exposure and development of a positive SARS-CoV-2 viral test
- Type of workplaces
- Level of community transmission (Table 2, Table 3)
- How many employees tested positive during previous rounds of testing
- Relevant experience with outbreaks at the workplace

Serial testing used in a screening program could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission, which is an occupational health measure of great importance in the types of workplaces mentioned above. Outbreak prevention and control is increasingly being thought to depend largely on the frequency of testing and the speed of reporting (an advantage of antigen tests) and is only marginally improved by the higher test sensitivity of NAATs. Serial testing, if implemented, should be integrated as a component of the comprehensive workplace program and not a substitute for other measures, such as COVID-19 vaccination, social distancing, mask wearing, hand hygiene, and cleaning and disinfection. Engineering controls and improved ventilation in settings such as office buildings and schools are also important.

Interpretation of screening SARS-CoV-2 test results

For screening testing, some antigen test results should be considered presumptive (preliminary results). A positive antigen screening test result should be considered presumptive when the pretest probability (likelihood that the person being tested actually has the infection) for COVID-19 is low or moderate for the purpose of making a clinical diagnosis (e.g., a worker who is asymptomatic and has no known exposures to COVID-19). Asymptomatic employees who have a positive antigen screening test result should undergo a confirmatory NAAT. They should not come to work and should quarantine during confirmatory testing.

According to test manufacturers, negative antigen tests results are presumptive for the purpose of making a clinical diagnosis. A negative antigen screening test result does not need to be followed by confirmatory testing if the pretest probability is low or serial antigen testing will be performed.

NAATs do not need to be routinely repeated for confirmation. Employees with a positive NAAT result should not come to work and should isolate at home. A negative NAAT result is interpreted as no evidence of SARS-CoV-2 infection at the time when the testing sample was collected. Employees who test negative should continue to take steps to protect themselves and others.

State, local, territorial, and tribal health departments may be able to provide assistance on any local context or guidance impacting the workplace. Before testing a large proportion of asymptomatic workers without known or suspected exposure, employers are encouraged to have a plan in place for how they will ensure access to clinical evaluation and confirmatory testing when needed, ensure test results are reported to public health departments, modify operations based on test results, collaborate with public health departments in workplace case investigation and contact tracing, and manage a higher risk of false positive results in a low prevalence population.

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Table 2. Community Indicators at the County Level[@]

Indicator	Low Transmission	Moderate Transmission	Substantial Transmission	High Transmission
Cumulative number of new cases per 100,000 persons within the last 7 days*	<10	10-49	50-99	≥100
Percentage of NAATs that are positive during the last 7 days[†]	<5%	5%-7.9%	8%-9.9%	≥10.0%

Indicators should be calculated for counties or core based statistical areas, although in rural areas with low population density, multiple jurisdictions might need to be combined to make the indicators more useful for decision-making. The indicators listed can be found by county on CDC's COVID Data Tracker Website under "county view".

[@] If the two indicators suggest different transmission levels, the higher level should be selected.

* Number of new cases in the county (or other administrative level) in the last 7 days divided by the population in the county (or other administrative level) and multiplying by 100,000.

[†] Number of positive tests in the county (or other administrative level) during the last 7 days divided by the total number of tests resulted in the county (or other administrative level) during the last 7 days. Calculating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Laboratory Test Percent Positivity: CDC Methods and Considerations for Comparisons and Interpretation.

Table 3. Potential Actions based on Community Indicator Level

Prevention Strategy	Low Transmission (Blue)	Moderate Transmission (Yellow)	Substantial Transmission (Orange)	High Transmission (Red)
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				

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Previous Updates

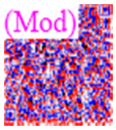
Updates from Previous Content

Revisions made on October 21, 2020

- Added links to the updated close contact definition.
- Updated language to align with updated definition.

Last Updated Mar. 17, 2021

Ib Centers for Disease Control and Prevention



COVI D-19

To maximize protection from the Delta variant and prevent possibly spreading it to others, get vaccinated as soon as you can and wear a mask indoors in public if you are in an area of substantial or high transmission.

Interim Guidance for SARS-CoV-2 Testing in Non-Healthcare Workplaces

Updated ~~Mar~~Oct. ~~17~~7, 2021

Summary of Recent Changes

Updates as of ~~March 17~~October 6, 2021

- Updated descriptions of test types.
- Updated to align with new antigen testing algorithms, one for community settings El and one for congregate settings p .
- ~~Added description of nucleic acid amplification tests (NAATs) and antigen tests as types of viral tests to align with the Overview of Testing for SARS-CoV-2~~
- ~~Added considerations on incorporating testing of asymptomatic individuals without known or suspected exposure to SARS-CoV-2 (screening testing) in select workplace settings as part of a workplace COVID-19 prevention and control plan~~
- Updated ~~considerations on frequency of~~ testing recommendations for fully vaccinated workers who are close contacts of someone with COVID-19.
- Clarified that screening testing recommendations apply to asymptomatic, unvaccinated workers.

View Previous Updates

Key Points

- Workplace-based testing for SARS-CoV-2, the virus that causes COVID-19, could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission. The purpose of this guidance is to provide employers with considerations for incorporating testing for SARS-CoV-2 into a workplace COVID-19 preparedness, response, and control plan in ~~select~~ non-healthcare workplaces.
- This guidance includes descriptions of different types of SARS-CoV-2 tests; scenarios where SARS-CoV-2 testing may be used; considerations for screening testing (testing asymptomatic and unvaccinated workers with no known or suspected exposure to SARS-CoV-2); and use of antigen tests for serial screening testing~~, including in high-density critical infrastructure workplaces~~.
- Screening testing could be effective in helping to prevent transmission for ~~select~~ workplace settings.
- These interim considerations on SARS-CoV-2 testing strategies for ~~select~~ non-healthcare workplaces during the COVID-19 pandemic are based on what is currently known about the transmission and severity of COVID-19 and is subject to change as additional information becomes available.

Note: This document provides guidance on the appropriate use of testing and does not dictate the determination of payment decisions or insurance coverage of such testing, except as may be otherwise referenced (or prescribed) by another entity or federal or state agency.

Introduction

The purpose of this document is to provide employers with strategies for consideration ofto consider for incorporating testing for SARS-CoV-2, the virus that causes COVID-19, into workplace preparedness, response, and control plans in select non-healthcare workplaces. For workplaces with healthcare personnel, including those that work in nursing homes, please refer to Interim Guidance on TestingInfection Prevention and Control Recommendations for Healthcare Personnel for SARS-CoV-2 and Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents and Healthcare Personnel.During the Coronavirus Disease 2019 (COVID-19) Pandemic and Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes.

Employers are encouraged to collaborate with state, territorial, tribal, and local health officials to determine whether and how to implement the following testing strategies and which one(s) would be most appropriate for their circumstances. These considerations are meant to supplement, not replace, any federal, state, local, territorial, or tribal health and safety laws, rules, and regulations with which workplaces must comply. These strategies should be carried out in a manner consistent with existing laws and regulations, including laws protecting employee privacy and confidentiality. They should also be carried out consistent with Equal Employment Opportunity Commission (EEOC) guidance EI regarding permissible testing policies and procedures. Employers paying forproviding testing of employees should put procedures in place for rapid notification of results and establish appropriate measures based on testing results, including instructions regarding self-isolation and restrictions on workplace access.

Considerations when testing

SARS-CoV-2 testing may be incorporated as part of a comprehensive approach to reducing transmission in non-healthcare workplaces. Symptom screening, testing, and contact tracing are strategies to identifyTesting identifies workers infected with SARS-CoV-2, the virus that causes COVID-19, so that actions can be taken to slow and stop the spread of the virus.
COVID-19 vaccine is currently available in limited doses; therefore, CDC's Advisory Committee on Immunization Practices (ACIP) described recommendations for prioritization during the early phases of the vaccination program. As vaccine supply increases and additional priority groups receive vaccine, CDC's priorities for SARS-CoV-2 testing will change and the guidance will be updated. For guidance on quarantine and testing of fully vaccinated people for COVID-19, please visit Interim Public Health Recommendations for Fully Vaccinated People.

Employees undergoing testing should receive clear information on:

- the manufacturer and name of the test, the type of test, the purpose of the test, the performance specifications of the test, any limitations associated with the test, who will pay for the test, how the test will be performed, how and when they will receive test results, and;
- how to understand what the results mean, actions associated with negative or positive results, the difference between testing for workplace screening versus for medical diagnosis, who will receive the results, how the results may be used, and any consequences for declining to be tested.

Individuals tested are required to receive patient fact sheets as part of the test's emergency use authorization EI (EUA).

According to the Americans with Disabilities Act (ADA), when employers implement any mandatory testing of employees, it must be 'job related and consistent with business necessity." In the context of the COVID-19 pandemic, the U.S. EEOC EI notes that testing to determine if an employee has SARS-CoV-2 infection with an "accurate and reliable test" is permissible as a condition to enter the workplace because an employee with the virus will "pose a direct threat to the health of others." EEOC notes that testing administered by employers that is consistent with current CDC guidance will meet the ADA's business necessity standard. However, workplace-based testing should not be conducted without the employee's consent. Employers who mandate workplace testing for SARS-CoV-2 infection should discuss further with employees who do not consent todecline testing and consider providing alternatives as feasible and appropriate, such as reassignment to tasks that can be performed via telework.

The Occupational Safety and Health Administration has issued interim guidance EI for enforcing the requirements of 29 CFR Part 1904 EI with respect to the recording of occupational illnesses, specifically cases of COVID-19. Under OSHA's

Under OSHA's recordkeeping requirements in 29 CFR Part 1904 EI , COVID-19 iscan be a recordable illness EI , and thus. Thus, employers are responsible for recording cases of COVID-19, if the case meets certain requirements. Employers are encouraged to frequently check OSHA's webpage at www.osha.gov/coronavirus EI for updates.

Test types

Viral tests

Viral tests ~~authorized EI by the Food and Drug Administration (FDA) are used to diagnose~~, including nucleic acid amplification tests (NAATs) and antigen tests, are used as diagnostic tests to detect infection with SARS-CoV-2~~, the virus that causes COVID-19. Viral tests evaluate whether the virus is present in respiratory or other specimens. Results from these tests help public health officials identify and isolate people who are infected to minimize SARS-CoV-2 transmission~~ and to inform an individual's medical care. Viral tests can also be used as screening tests to reduce the transmission of SARS-CoV-2 by identifying infected persons who need to isolate from others. See FDA's list of In Vitro

Diagnostics Emergency Use Authorizations EI for more information about the performance of specific authorized tests.

- Nucleic acid amplification tests (NAATs), such as real-time reverse transcription-polymerase chain reaction (RT-PCR), detect viral ribonucleic acid (RNA) and indicate a current infection or a recent infection with prolonged viral RNA detection but without direct evidence for virus capable of replicating or of being transmitted to others. NAATs are high-sensitivity, high-specificity tests for diagnosing SARS-CoV-2 infection. NAATs detect genetic material (nucleic acids). NAATs for SARS-CoV-2 specifically identify the ribonucleic acid (RNA) sequences that comprise the genetic material of the virus. Most NAATs need to be processed in a laboratory with variableand time to results can vary (-1 21-3 days), but some NAATs are point-of-care (POC) tests with results available in about 15-45 minutes. Because laboratory-based NAATs are considered the most sensitive tests for detecting SARS-CoV-2, they can also be used to confirm the results of lower sensitivity tests, such as POC NAATs or antigen tests.
- Antigen tests are immunoassays that detect the presence of a specific viral antigen. Antigen tests generally have similar specificity but are less sensitive than most NAATs. Most can be processed at the point of care with results available in about 15-30 minutes. Antigen tests generally have similar specificity but are less sensitive than NAATs. Depending on the pre-test probability,minutes and thus can be used in screening programs to quickly identify those who are likely to be contagious. Because of the performance characteristics of antigen tests, it may be necessary to confirm some antigen test results may need confirmation with a NAAT (e.g., a negative test in persons with symptoms or a positive test in persons without symptoms). Use of the Antigen Testing Algorithm 0 [147 KB, 1 page] with a laboratory-based NAAT. Furthermore, based on the authorization from FDA EI , some point-of-care NAATs cannot be used for confirmatory testing. Use of the appropriate antigen testing algorithm is recommended to determine when confirmatory testing is needed.

Antibody tests

Antibody (or serology) tests are used to detect previous infection with SARS-CoV-2 and can aid in the diagnosis of Multisystem Inflammatory Syndrome in Childrenmultisystem inflammatory syndrome in children (MIS-C) and in adults (MIS-A). CDC does not recommend using antibody testing to diagnose current infection. Depending on the time when someone was infected and the timing of the test, the test might not detect antibodies in someone with a current infection. In addition, it is not currently known whether a positive antibody test result indicates protective immunity against SARS-CoV-2; therefore, at this time, antibody tests should not be used to determine if an individual is immune against reinfection. Antibody testing is being used for public health surveillance and epidemiologic purposes. Because antibody tests can have different targets on the virus, specific tests might be needed to assess for antibodies originating from past infection versus those from vaccination. For more information about COVID-19 vaccines and antibody test results, refer to Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Approved or Authorized in the United States.

For more information, please refer to Overview of Testing for SARS-CoV-2 (COVID-19).

Overview of testing scenarios

Diagnostic testing is intended to identify current infection in individuals and is performed when a person has signs or symptoms consistent with COVID-19, or when a person is asymptomatic but has a recent known or suspected exposure to SARS-CoV-2.

Examples of diagnostic testing include:

- Testing people who have symptoms consistent with COVID-19 and who present to their healthcare provider
- Testing people as a result of contact tracing efforts
- Testing people who indicate that they were exposed to someone with a confirmed or suspected case of COVID-19.
- Testing people who attended an event where another attendee was later confirmed to have COVID-19

Screening tests are intended to identify infected people who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that measures can be taken to prevent

further transmission.

Examples of screening testing include:

- Testing unvaccinated employees in a workplace setting
- Testing unvaccinated students, faculty, and staff in a K-12 school or ~~university~~institute of higher education setting
- Testing ~~a~~an unvaccinated person before or after travel

Testing at home for someone who does not have symptoms associated with COVID-19 and no known exposures to someone with COVID-19

Choosing a test

When choosing which test to use, it is important to understand the purpose of the testing (e.g., diagnostic~~,~~ vs. screening), analytic performance of the test within the context of the level of community transmission, need for rapid results, and other considerations~~.~~ (See Table 1). The COVID-19 Viral Testing Tool helps healthcare providers and individuals understand their COVID-19 testing options. After test results are in, the tool can help interpret results and guide next steps.

Table 1 summarizes some characteristics of NAATs and antigen tests to consider. Most antigen tests that have received ~~EUA~~cut, from FDA CI are authorized for testing symptomatic persons within the first 5, 6, 7, 12, or 14 days of symptom onset. ~~Given the risk of transmission of SARS-CoV-2 from asymptomatic and presymptomatic persons with SARS-CoV-2 infection, use~~Accumulation of data on the performance of antigen tests in ~~asymptomatic and presymptomatic persons can be considered. FDA has provided a list of FAQ~~different situations has helped guide the use of these tests as screening tests in asymptomatic people to detect or exclude SARS-CoV-2 infection. See FDA's recommendations for healthcare providers ~~who are~~ using SARS-CoV-2 diagnostic tests ~~in~~for screening asymptomatic individuals ~~CI , and~~for COVID-19 CI . Also see information from the Centers for Medicare & Medicaid Services ~~will temporarily exercise enforcement discretion ■ [40 KB, 1 Page] EI to enable the use of antigen tests in asymptomatic individuals for the duration of the COVID-19 public health emergency under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)~~(CMS) on Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion ■ CI . Laboratories that perform screening or diagnostic testing for SARS-CoV-2 must have a ~~CLIA~~Clinical Laboratory Improvement Amendments (CLIA) certificate and meet regulatory requirements. Tests that have received an EUA from FDA for ~~point of care (POC)~~ use can be performed with a CLIA certificate of waiver.

Table 1. NAAT and Antigen Test Differences to Consider When Planning for Diagnostic or Screening Use

NAATs

Antigen Tests

Intended Use

Detect *current* infection

Detect *current* infection

Analyte Detected

Viral Ribonucleic Acid (RNA)

Viral Antigens

Specimen Type(s)

Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva

Nasal, Nasopharyngeal

Sensitivity

Varies by test, but generally high for laboratory-based tests and ~~moderate-high~~moderate-to-high for ~~point of care (~~POC~~)~~ tests

Varies depending on the course of infection, but generally moderate-to-high at times of peak viral load*

Specificity

High

High

Test Complexity

Varies by ~~Test~~test

Relatively ~~Easy~~easy to ~~Use~~use

Authorized for Use at the Point-of-Care

Most are not, some are

Most are, some are not

Turnaround Time

Most 1-3 days. Some could be rapid in 15 minutes

Ranges from 15 minutes to 30 minutes

Cost/Test^

Moderate (--$75-$100/test)

Low (-$5-$50/test)

Advantages

Most sensitive test method available

Short turnaround time for NAAT POC tests, but few available

Usually does not need to be repeated to confirm results

Short turnaround time (approximately 15 minutes)~~.~~+

When performed at or near POC, allows for rapid identification of infected people, thus preventing further virus transmission in the community, workplace, etc.

Comparable performance to NAATs in symptomatic persons and/or if culturable virus present, when the person is presumed to be infectious

Disadvantages

Longer turnaround time for lab-based tests (1-3 days)

Higher cost per test

A positive NAAT diagnostic test should not be repeated within 90 days, because people may continue to have detectable RNA after risk of transmission has passed

May need confirmatory testing

Less sensitive (more false negative results) compared to NAATs, especially among asymptomatic people

**The decreased sensitivity of antigen tests might be offset if the POC antigen tests are repeated more frequently (i.e., serial testing at least weekly).
Costs for: NAATs ~~CI, Antibody tests CI~~EI
+Refers to point-of-care antigen tests only.

Considerations for testing in different scenarios

Diagnostic testing

Testing persons with signs or symptoms consistent with COVID-19

Employers may consider conducting daily in-person or virtual health checks (e.g., symptom and temperature screening) to identify employees with signs or symptoms consistent with COVID-19 before they enter a facility~~, in accordance with CDC's Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19)~~. Employers should follow guidance from the ~~EEOC~~EEOCexternal icon CI regarding confidentiality of medical records from health checks.

Vaccinated and unvaccinated workers with COVID-19 symptoms should be immediately separated from other employees, customers, and visitors, and sent home or to a healthcare facility, depending on how severe their symptoms are, and follow CDC guidance for caring for oneself. To prevent stigma and discrimination in the workplace, make employee health screenings as private as possible. CDC recommends that anyone with signs or symptoms of COVID-19 be tested and follow the advice of their healthcare provider. Waiting for test results prior to returning to work is recommended to keep potentially infected workers out of the workplace.

Employers are encouraged to implement flexible sick leave and supportive policies and practices as part of a comprehensive approach to prevent and reduce transmission among employees.

Positive test results using a viral test (NAAT or antigen) in persons with signs or symptoms consistent with COVID-19 indicate that the ~~person has COVID-19. A negative antigen test in persons with signs or symptoms of COVID-19 should be confirmed by a laboratory-based NAAT, a more sensitive test. Results from NAATs are considered the definitive result when there is a discrepancy between the antigen and NAAT test. For more information, see the Antigen Test Algorithm ■ [458 KB, 1 Page]. Positive test results should be interpreted to indicate that a~~ person has COVID-19 and should not come to work and should isolate at home. Decisions to discontinue isolation for workers with COVID-19 and allow them to return to the workplace may follow either a symptom-based, time-based, or a test-based strategy (see Testing to determine resolution of infection below).

A negative antigen test in persons with signs or symptoms of COVID-19 should be confirmed by a laboratory-based NAAT, a more sensitive test. Results from NAATs are considered the definitive result when there is a discrepancy between the antigen and NAAT test. For more information, see the antigen test algorithms for community settings ■ and congregate settings I .

Testing asymptomatic persons with recent known or suspected exposure to SARS-CoV-2

~~Case investigation~~ is typically initiated when a health department receives a report from a laboratory or testing site of a positive SARS-CoV-2 viral test result, or a report from a healthcare provider of a patient with a confirmed or probable diagnosis of COVID-19 .

~~In general, fully vaccinated workers with no COVID-like symptoms do not need to quarantine or be tested following an exposure to someone with suspected or confirmed COVID-19. However, those who work in congregate settings or other high-density workplaces (e.g., meat and poultry processing and manufacturing plants) should be tested after an exposure;~~

Fully vaccinated people who have come into close contact with someone with COVID-19 should be tested 3-5 days following the date of their exposure and wear a mask in public indoor settings for 14 days or until ~~however,~~ they ~~do not need to quarantine~~receive a negative test result. They should isolate if they test positive. For more guidance on quarantine and testing of fully vaccinated people, please visit Interim Public Health Recommendations for Fully Vaccinated People.

Viral testing is recommended for all unvaccinated close contacts ~~(people who have been within 6 feet for a combined total of 15 minutes or more during a 24-hour period) of persons with COVID-19~~. Because of the potential for asymptomatic ~~and~~(not having symptoms) or pre-symptomatic (not yet showing symptoms) transmission of SARS-CoV-2, it is important that unvaccinated individuals exposed to people with known or suspected COVID-19 be quickly identified and quarantined. Viral testing with NAATs or antigen tests can detect if these individuals are currently infected.

The health department may ask the employer for assistance in identifying close contacts of the worker with SARS-CoV-2 infection. Employers are encouraged to work with public health departments investigating cases of COVID-19 and tracing contacts to help reduce the spread of SARS-CoV-2 in their workplaces and communities.

Because there may be a delay between the time a person is exposed to the virus and the time that virus can be detected by testing, early testing after exposure at a single time point may miss many infections. Testing that is repeated at different points in time, also referred to as serial testing, is more likely to detect infection among close contacts of a COVID-19 case than testing done at a single point in time. Viral testing is recommended for unvaccinated close contacts of persons with COVID-19 ~~who should be tested~~ immediately after being identified, and if negative, ~~tested~~ again in 5-7 days after last exposure or

immediately if symptoms develop during quarantine.

While CDC continues to recommend a 14-day quarantine for unvaccinated individuals who are close contacts of a person with COVID-19, viral testing may also be used as part of an option to shorten the quarantine period. Local public health authorities determine and establish the quarantine options for their jurisdictions. Shortening quarantine may increase willingness to adhere to public health recommendations. However, shortened quarantines with continued symptom monitoring and masking until Day 14 may be less effective in preventing transmission of COVID-19 than the currently recommended ~~14 day~~ quarantine. In jurisdictions with shortened quarantine options, workplaces with higher risk of SARS-CoV-2 introduction or transmission, or with potential for greater negative impact if employees become infected SARS-CoV-2 (see ~~Types of~~ workplaces below), can consider restricting unvaccinated workers from entering the workplace until 14 days after their exposure.

~~Testing~~Viral testing may also be considered for unvaccinated persons who might have been in close contact with persons diagnosed with COVID-19 in collaboration with the local health department if resources permit. A risk-based approach to testing possible contacts of a person with confirmed COVID-19 may be applied. Such an approach should take into consideration the likelihood of exposure, which is affected by the characteristics of the workplace and the results of contact investigations. In some settings, expanded screening testing (i.e., testing beyond individually identified close contacts to those who are possible close contacts), such as targeting workers who worked in the same area and during the same shift, may be considered as part of a strategy to control the transmission of SARS-CoV-2 in the workplace. Employers are encouraged to consult with local, territorial, and tribal health departments to help inform decision-making about expanded screening testing.

High-risk settings that have demonstrated potential for rapid and widespread dissemination of SARS-CoV-2 include:

- ~~High-density critical infrastructure workplaces,~~Workplaces where workers are in the workplace for long periods (e.g., for 8-12 hours per shift) and have prolonged close contact with coworkers
- Workplaces where employees live in congregate settings CI (e.g., fishing vessels, offshore oil platforms, farmworker housing, or wildland firefighter camps)
- Workplaces with populations at increased risk for severe illness if they are infected, such as ~~homeless shelters~~ and workplaces with older workers

~~After a case of COVID-19 has been identified in a high-density critical infrastructure workplace, where workers are in prolonged close contact, NAAT or antigen testing can be used to diagnose infection in workers with known or suspected exposure to SARS-CoV-2. Employers are encouraged to consult with state, local, territorial, and tribal health departments to help inform decision-making about expanded screening testing.~~

If employees are tested after close contact or suspected close contact with someone who has a confirmed or probable diagnosis of COVID-19, care should be taken to inform these employees of their possible exposure to SARS-CoV-2 in the workplace while maintaining confidentiality of the individual with COVID-19, as required by the ADA ~~CI~~CJ and consistent with EEOC guidance regarding What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws

Testing to determine resolution of infection

The decision to end isolation and return to the workplace for employees with suspected or confirmed SARS-CoV-2 infection should be made in the context of clinical and local circumstances. NAATs have detected SARS-CoV-2 RNA in some recovered people's respiratory specimens for up to 3 months after illness onset but without direct evidence that virus that can replicate or cause disease. Consequently, evidence supports a time-based and symptom-based strategy to determine when to discontinue isolation or other precautions rather than a test-based strategy. For persons who are severely immunocompromised, a test-based strategy could be considered in consultation with infectious disease experts. For all others, a test-based strategy is no longer recommended except to discontinue isolation or precautions earlier than would occur under the symptom-based strategy.

Under the ADA, employers are permitted to require a healthcare provider's note ~~CI~~EI to verify that employees are healthy and able to return to work. However, as a practical matter, employers should be aware that healthcare provider offices and medical facilities may be extremely busy during periods when community COVID-19 indicators are in the moderate to high ~~categorizations~~categories (Table 2) and may not be able to provide such documentation in a timely manner. In such cases, employers should consider not requiring a healthcare provider's note for employees who are sick to validate their illness, qualify for sick leave, or to return to work. Most people with COVID-19 have mild illness, can recover at home without medical care, and can follow CDC recommendations to determine when to discontinue isolation and return to the workplace.

Screening testing

Testing asymptomatic persons without known or suspected exposure to SARS-CoV-2 for early identification, isolation, and disease prevention

When to consider screening testing

Screening testing of asymptomatic in non-healthcare settings of unvaccinated workers without known or suspected exposure to SARS-CoV-2 in select non-healthcare settings may be useful to detect COVID-19 early and stop transmission quickly, particularly in areas with community COVID-19 indicators in the moderate to high categorizations categories (Table 2, Table 3). Screening testing can be used in addition to symptom and temperature checks, which will miss asymptomatic or presymptomatic pre-symptomatic contagious workers. Persons with asymptomatic or presymptomatic pre-symptomatic SARS-CoV-2 infection are significant contributors to SARS-CoV-2 transmission.

In general, fully vaccinated workers should continue to follow employer guidance on screening testing. Please see Interim Public Health Recommendations for Fully Vaccinated People for more information.

Types of workplaces

Workplace settings for which screening testing of unvaccinated, asymptomatic workers should be considered include:

- Large workplaces
- Workplaces at increased risk of introduction of SARS-CoV-2 (e.g., workplaces where workers are in close contact with the public, such as restaurants or salons, or workplaces in communities with moderate to high transmission)
- Workplaces where there is a higher risk of SARS-CoV-2 transmission (e.g., workplaces where physical distancing is difficult and workers might be in close contact, such as manufacturing or food processing plants, or workplaces that provide congregate housing for employees such as fishing vessels, offshore oil platforms, farmworker housing or wildland firefighter camps)
- Workplaces where SARS-CoV-2 infection among employees will lead to greater negative impact, such as
  - Workplaces in remote settings where medical evaluation or treatment may be delayed
  - Workplaces where continuity of operations is a high priority (e.g., critical infrastructure sectors EI)
  - Workplaces with a high proportion of employees at increased risk for severe illness

Frequency of screening testing

Approaches may include initial testing of all workers before entering a workplace, periodic testing of workers at regular intervals, targeted testing of new workers or those returning from a prolonged absence (such as medical leave or furlough), or some combination of approaches. Given the incubation period for COVID-19 (up to 14 days), CDC recommends conducting screening testing of unvaccinated, asymptomatic workers without known or suspected exposures at least weekly. Employers

may find the following factors helpful to consider when determining the interval for periodic testing:

- The availability of testing, turnaround time, and cost
- The latency time period between exposure and development of a positive SARS-CoV-2 viral test
- Type of ~~workplaces~~workplace
- Level of community transmission (Table 2, Table 3)
- ~~How many~~Number of employees who tested positive during previous rounds of testing
- Relevant experience with outbreaks at the workplace

Serial testing used in a screening program could identify workers with SARS-CoV-2 infection, and thus help prevent or reduce further transmission, which is an occupational health measure of great importance in the types of workplaces mentioned above. Outbreak prevention and control is increasingly being thought to depend largely on the frequency of testing and the speed of reporting (an advantage of antigen tests) and is only marginally improved by the higher test sensitivity of NAATs. Serial testing, if implemented, should be integrated as a component of the comprehensive workplace program and not a substitute for other measures, such as COVID-19 vaccination, ~~social~~physical distancing, mask wearing, hand hygiene, and cleaning and disinfection. Engineering controls and improved ventilation in settings such as office buildings and schools are also important.

Interpretation of screening SARS-CoV-2 test results

For screening testing, some antigen test results should be considered presumptive (preliminary results). A positive antigen screening test result should be considered presumptive when the pretest probability (likelihood that the person being tested actually has the infection) for COVID-19 is low or moderate for the purpose of making a clinical diagnosis (e.g., a worker who is asymptomatic and has no known exposures to COVID-19). within the last 14 days, is fully vaccinated, or has had a SARS-CoV-2 infection in the last 3 months). Please see Evaluating the Results of Antigen Testing for SARS-CoV-2.

Asymptomatic employees who have a positive antigen screening test result should undergoand need a confirmatory NAAT. They should not come to work and should quarantine during confirmatory testing. For confirmatory testing, CDC recommends using a laboratory-based NAAT that has been evaluated against the FDA reference panel for analytical sensitivity. See FDA's SARS-CoV-2 Reference Panel Comparative Data CI

According to test manufacturers, negative antigen tests results are presumptive for the purpose of making a clinical diagnosis. A negative antigen screening test result does not need to be followed by confirmatory testing if the pretest probability is low or serial antigen testing will be performed.

NAATs that generate presumptive results are not appropriate for use in confirmatory testing.

NAATs do not need to be routinely repeated for confirmation. Employees with a positive confirmatory NAAT result should not come to work and should isolate at home. A negative confirmatory NAAT result is interpreted as no evidence of SARS-CoV-2 infection at the time when the testing sample was collected. Employees who test negative should continue to take steps to protect themselves and others.

State, local, territorial, and tribal health departments may be able to provide assistance on any local context or guidance impacting the workplace. Before testing a large proportion of asymptomatic workers without known or suspected exposure, employers are encouraged to have a plan in place for how they will ensure access to clinical evaluation and confirmatory testing when needed, ensure test results are reported to public health departments, modify operations based on test results, collaborate with public health departments in workplace case investigation and contact tracing, and manage a higher risk of false positive results in a low prevalence population.

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Table 2. Level of Community Indicators at the County Level@Transmission

Indicator	Low Transmission	Moderate Transmission	Substantial Transmission	High Transmission
Cumulative number of new cases per 100,000 persons within the last 7 days*	<10	10-49	50-99	≥
Percentage of NAATs that are positive during the last 7 †	<5%	5%-7.9%	8%-9.9%	≥

Indicators should be calculated for counties or core based statistical areas, although in rural areas with low population density, multiple jurisdictions might need to be combined to make the indicators more useful for decision-making. The indicators listed can be found by county on CDC's COVID ~~Data Tracker Website under "county view"~~-19 Integrated County View.

~~@ If the two indicators suggest different transmission levels, the higher level should be selected.~~

* Number of new cases in the county (or other administrative level) in the last 7 days divided by the population in the county (or other administrative level) and multiplying by 100,000.

† Number of positive tests in the county (or other administrative level) during the last 7 days divided by the total number of ~~+~~ tests resulted in the county (or other administrative level) during the last 7 days. Calculating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Laboratory Test Percent Positivity: CDC Methods and Considerations for Comparisons and Interpretation.

Table 3. Potential Actions ~~based~~Based on Community ~~Indicator~~Transmission Level

Prevention Strategy	Low Transmission (Blue)	Moderate Transmission (Yellow)	Substantial Transmission (Orange)	High Transmission (Red)
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Facilitate diagnostic testing for symptomatic persons and all close contacts of cases				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				
Implement screening testing of select groups at least weekly plus facilitate diagnostic testing of symptomatic persons and close contacts				

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Previous Updates

Updates from Previous Content

Updates as of March 17, 2021

- Added description of nucleic acid amplification tests (NAATs) and antigen tests as types of viral tests to align with the Overview of Testing for SARS-CoV-2.
- Added considerations on incorporating testing of asymptomatic individuals without known or suspected exposure to SARS-CoV-2 (screening testing) in select workplace settings as part of a workplace COVID-19 prevention and control plan.
- Updated considerations on frequency of testing.

~~Revisions made on~~**Updates as of October 21, 2020**

- Added links to the updated close contact definition.
- Updated language to align with updated definition.

Last Updated ~~Mar~~Oct. ~~17~~7, 2021

The Wayback Machine - https://web.archive.org/web/20220827133701/https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antig...

At-Home COVID-19 Antigen Tests-Take Steps to Reduce Your Risk of False Negative: FDA Safety Communication

Date Issued: August 11, 2022



Perform repeat, or serial testing following a negative result on any at-home COVID-19 test, whether or not you have symptoms.

The U.S. Food and Drug Administration (FDA) is advising people to perform repeat, or serial, testing following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result) and to help prevent people from unknowingly spreading the SARS-CoV-2 virus to others. **The FDA recommends repeat testing following a negative result whether or not you have COVID-19 symptoms.**

At-home COVID-19 antigen tests detect proteins, called antigens, from the SARS-CoV-2, the virus that causes COVID-19. At-home COVID-19 antigen tests are less likely to detect the SARS-CoV-2 virus than molecular tests, such as polymerase chain reaction (PCR) tests. This is especially true early in an infection or in people who do not have COVID-19 symptoms. Currently, all at-home COVID-19 antigen tests are FDA-authorized for repeat, or serial use. This means people should use multiple tests over a certain time period, such as 2-3 days, especially when the people using the tests don't have COVID-19 symptoms. Today, the FDA is highlighting the continued need for repeat, or serial testing when people get a negative result with an at-home COVID-19 antigen test, including recommending additional testing over a longer period of time..

Over the course of the COVID-19 pandemic, public health scientists have continued to learn about the SARS-CoV-2 virus and the impact of variants on diagnostic tests that detect SARS-CoV-2. Today's recommendations are based on the latest study results from people with likely omicron infection showing that repeat testing after a negative at-home COVID-19 antigen test result increases the chance of an accurate result. COVID-19 diagnostic testing remains a cornerstone of our nation's fight against COVID-19. At-home COVID-19 antigen tests, while not perfect, provide a fast and convenient COVID-19 testing option.

Recommendations:

Before you use a COVID-19 antigen test:

- Be aware that at-home COVID-19 antigen tests are less accurate than molecular tests. COVID-19 antigen tests may not detect the SARS-CoV-2 virus early in an infection, meaning testing soon after you were exposed to someone with COVID-19 could lead to a false-negative result, especially if you don't have symptoms. This is the reason why repeat testing is important.
- If you plan to use at-home COVID-19 antigen tests, have several tests on hand so you can test more than once. You do not need to use the same brand of test each time for repeat testing. Visit At-Home OTC COVID-19 Diagnostic Tests (/web/20220827133701/https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests) for a list of all FDA-authorized home tests and for more information about who can use a test and for what ages.
- Be aware the FDA expects similar performance with Point of Care (POC) COVID-19 antigen tests performed at a clinic or doctor's office. A negative POC COVID-19 antigen test result should also be followed up with repeat, or serial testing, and an at-home test could be used.

When you use an at-home COVID-19 antigen test:

Follow the test's step by step instructions exactly to perform the test and to read the test's results.

After you use an at-home COVID-19 antigen test:

- **If you receive a positive result initially or after a repeat test**, this means the test detected the SARS-CoV-2 virus and you most likely have COVID-19.
    - Follow the Centers for Disease Control and Prevention (CDC) guidance (https://web.archive.org/web/20220827133701/https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html) for people with COVID-19, including to stay home, isolate from others, and seek follow-up care with a health care provider to determine the next steps.
- **If you receive a negative result,** the test did not detect the SARS-CoV-2 virus at the time of that test.
    - **If you have COVID-19 symptoms (https://web.archive.org/web/20220827133701/https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html), test again 48 hours after the first negative test, for a total of at least two tests.**
        - If you get a negative result on the second test and you are concerned that you could have COVID-19, you may choose to test again 48 hours after the second test, consider getting a laboratory molecular-based test, or call your health care provider.
    - **If you do not have COVID-19 symptoms and believe you have been exposed to COVID-19, test again 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.**
        - If you get a negative result on the second test, test again 48 hours after the second test.

    - If you get a negative result on the third test and you are concerned that you could have COVID-19, you may choose to test again using an antigen test, consider getting a laboratory molecular-based test, or call your health care provider.
- **If you get a positive result on any repeat test with an at-home COVID-19 antigen test**, you most likely have COVID-19 and should follow the CDC guidance for people with COVID-19.

Background

COVID-19 diagnostic tests (/web/20220827133701/https://www.fda.gov/consumers/consumer-updates/covid-19-test-basics) detect the SARS-CoV-2 virus. At-home COVID-19 diagnostic tests are FDA-authorized (/web/20220827133701/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) for self-testing at home, or anywhere. The FDA has authorized both molecular and antigen COVID-19 diagnostic tests for home use.

Overall performance of at-home COVID-19 antigen tests

Most at-home COVID-19 tests are antigen tests and do not detect the SARS-CoV-2 virus as well as molecular tests, most of which are laboratory-based such as polymerase chain reaction (PCR) tests. Molecular COVID-19 tests are generally expected to detect the SARS-CoV-2 virus at least 95% of the time when someone is infected. However, at-home COVID-19 antigen tests are generally expected to detect the SARS-CoV-2 virus at least 80% of the time when someone is infected.

When you perform an at-home COVID-19 antigen test, and you get a positive result, the results are typically accurate. However, if you perform an at-home COVID-19 antigen test, you could get a false negative result. This means that the test may not detect the SARS-CoV-2 virus that is in your nasal swab sample. This could happen if you test soon after you get an infection, especially if you don't have COVID-19 symptoms (https://web.archive.org/web/20220827133701/https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html). If you receive a false negative test result, you may unknowingly spread the SARS-CoV-2 virus to others.

Studies to better understand at-home COVID-19 antigen test performance

When at-home COVID-19 antigen tests were initially FDA-authorized, the FDA knew that for people to get accurate results, test instructions would need to include directions for repeat, or serial, testing. The FDA believed the best way to better understand COVID-19 infections and evaluate test accuracy was to require test developers to perform follow up studies with their tests. The studies would need to assess how well COVID-19 antigen tests could detect the SARS-CoV-2 virus, especially in people without COVID-19 symptoms. Therefore, the FDA required each at-home COVID-19 antigen test manufacturer to assess how well their test works when used by people with and without COVID-19 symptoms following repeat testing instructions.

In parallel, the FDA collaborated with the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School and together they designed a comprehensive study (https://web.archive.org/web/20220827133701/https://www.medrxiv.org/content/10.1101/2022.08.04.22278274v1) (https://web.archive.org/web/20220827133701mp_/http://www.fda.gov/about-fda/website-

policies/website-disclaimer) to assess at-home COVID-19 antigen test performance. The study was funded by the NIH's Rapid Acceleration Diagnostics (RADx) Program and included more than 7,000 participants. The results of the study would be available as a resource to all at-home COVID-19 antigen test manufacturers.

The study participants collected their nasal sample and performed an at-home COVID-19 antigen test. Participants who got a negative test result performed repeat testing every 48 hours, over 14 days. All participants also collected their nasal sample using a home collection kit and then sent the sample to clinical laboratory for testing with an FDA-authorized molecular test. The study compared the performance of at-home COVID-19 antigen tests to performance of a laboratory-based molecular test. Results from this study (https://web.archive.org/web/20220827133701/https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1) (https://web.archive.org/web/20220827133701mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer) show that repeat testing over a longer timeframe improves test performance and increases the likelihood that an at-home COVID-19 antigen test will detect an infection. These results have further guided the FDA's thinking that repeat testing after a negative result with an at-home COVID-19 antigen test reduces the risk of a false negative result.

FDA Actions

The FDA is committed to appropriately accurate and reliable at-home COVID-19 diagnostic tests for all Americans and will keep the public informed if significant new information about COVID-19 antigen test performance becomes available.

The FDA is working collaboratively with government and academic partners to perform studies and make the results of these studies available.

The FDA encourages at-home COVID-19 antigen test developers with a current Emergency Use Authorization (EUA) to engage with us about how they may be able to use these study results.

Reporting Problems with Your Device

If you think you had a problem with your COVID-19 test, the FDA encourages you to report the problem through the MedWatch Voluntary Reporting Form (https://web.archive.org/web/20220827133701/https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home).

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Questions?

If you have questions, email the Division of Industry and Consumer Education (DICE) at DICE@FDA.HHS.GOV (https://web.archive.org/web/20220827133701/mailto:DICE@FDA.HHS.GOV) (https://web.archive.org/web/20220827133701mp_/http://www.fda.gov/about-fda/website-policies/website-disclaimer) or call 800-638-2041 or 301-796-7100.

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What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws

Technical Assistance Questions and Answers - Updated on April 23, 2020

- *All EEOC materials related to COVID-19 are collected at www.eeoc.gov/coronavirus.*
- The EEOC enforces workplace anti-discrimination laws, including the Americans with Disabilities Act (ADA) and the Rehabilitation Act (which include the requirement for reasonable accommodation and non-discrimination based on disability, and rules about employer medical examinations and inquiries), Title VII of the Civil Rights Act (which prohibits discrimination based on race, color, national origin, religion, and sex, including pregnancy), the Age Discrimination in Employment Act (which prohibits discrimination based on age, 40 or older), and the Genetic Information Nondiscrimination Act.
- The EEO laws, including the ADA and Rehabilitation Act, continue to apply during the time of the COVID-19 pandemic, but they do not interfere with or prevent employers from following the guidelines and suggestions made by the CDC or state/local public health authorities about steps employers should take regarding COVID-19. **Employers should remember that guidance from public health authorities is likely to change as the COVID-19 pandemic evolves. Therefore, employers should continue to follow the most current information on maintaining workplace safety.**
- The EEOC has provided guidance (a publication entitled Pandemic Preparedness in the Workplace and the Americans With Disabilities Act [PDF version]), consistent with these workplace protections and rules, that can help employers implement strategies to navigate the impact of COVID-19 in the workplace. This pandemic publication, which was written during the prior H1N1 outbreak, is still relevant today and identifies established ADA and Rehabilitation Act principles to answer questions frequently asked about the workplace during a pandemic. It has been updated as of March 19, 2020 to address examples and information regarding COVID-19; **the new 2020 information appears in bold.**
- The World Health Organization (WHO) has declared COVID-19 to be an international pandemic. The EEOC pandemic publication includes a separate section that answers common employer questions about what to do after a pandemic has been declared. Applying these principles to the COVID-19 pandemic, the following may be useful:

A. Disability-Related Inquiries and Medical Exams

A.1. How much information may an employer request from an employee who calls in sick, in order to protect the rest of its workforce during the COVID-19 pandemic? *(3/17/20)*

During a pandemic, ADA-covered employers may ask such employees if they are experiencing symptoms of the pandemic virus. For COVID-19, these include symptoms such as fever, chills, cough, shortness of breath, or sore throat. Employers must maintain all information about employee illness as a confidential medical record in compliance with the ADA.

A.2. When screening employees entering the workplace during this time, may an employer only ask employees about the COVID-19 symptoms EEOC has identified as examples, or may it ask about any symptoms identified by public health authorities as associated with COVID-19? *(4/9/20)*

As public health authorities and doctors learn more about COVID-19, they may expand the list of associated symptoms. Employers should rely on the CDC, other public health authorities, and reputable medical sources for guidance on emerging symptoms associated with the disease. These sources may guide employers when choosing questions to ask employees to determine whether they would pose a direct threat to health in the workplace. For example, additional symptoms beyond fever or cough may include new loss of smell or taste as well as gastrointestinal problems, such as nausea, diarrhea, and vomiting.

A.3. When may an ADA-covered employer take the body temperature of employees during the COVID-19 pandemic? *(3/17/20)*

Generally, measuring an employee's body temperature is a medical examination. Because the CDC and state/local health authorities have acknowledged community spread of COVID-19 and issued attendant precautions, employers may measure employees' body temperature. However, employers should be aware that some people with COVID-19 do not have a fever.

A.4. Does the ADA allow employers to require employees to stay home if they have symptoms of the COVID-19? *(3/17/20)*

(https://web.archive.org/web/20210712111809/https://www.askjan.org/) as a resource for different types of accommodations. JAN's materials about COVID-19 are available at **https://askjan.org/topics/COVID-19.cfm (https://web.archive.org/web/20210712111809/https://askjan.org/topics/COVID-19.cfm)**. Employers also may consult applicable **Occupational Safety and Health Administration (OSHA) COVID-specific resources (https://web.archive.org/web/20210712111809/https://www.osha.gov/SLTC/covid-19/)**. Even if there is no reasonable accommodation that will allow the unvaccinated employee to be physically present to perform his or her current job without posing a direct threat, the employer must consider if telework is an option for that particular job as an accommodation and, as a last resort, whether reassignment to another position is possible.

The ADA requires that employers offer an available accommodation if one exists that does not pose an undue hardship, meaning a significant difficulty or expense. See 29 C.F.R. 1630.2(p). Employers are advised to consider all the options before denying an accommodation request. The proportion of employees in the workplace who already are partially or fully vaccinated against COVID-19 and the extent of employee contact with non-employees, who may be ineligible for a vaccination or whose vaccination status may be unknown, can impact the ADA undue hardship consideration. Employers may rely on **CDC recommendations (https://web.archive.org/web/20210712111809/https://www.cdc.gov/coronavirus/2019-ncov/)** when deciding whether an effective accommodation is available that would not pose an undue hardship.

Under the ADA, it is unlawful for an employer **to disclose that an employee is receiving a reasonable accommodation (https://web.archive.org/web/20210712111809/https://www.eeoc.gov/laws/guidance/enforcement-guidance-reasonable-accommodation-and-undue-hardship-under-ada#li42)** or **to retaliate against an employee for requesting an accommodation (https://web.archive.org/web/20210712111809/https://www.eeoc.gov/laws/guidance/enforcement-guidance-reasonable-accommodation-and-undue-hardship-under-ada#li19)**.

K.7. If an employer requires employees to get a COVID-19 vaccination from the employer or its agent, do the ADA's restrictions on an employer making disability-related inquiries or medical examinations of its employees apply to any part of the vaccination process? *(12/16/20, updated 5/28/21)*

Yes. The ADA's restrictions apply to the screening questions that must be asked immediately prior to administering the vaccine if the vaccine is administered by the employer or its agent. An **employer's agent (https://web.archive.org/web/20210712111809/https://www.eeoc.gov/laws/guidance/section-2-threshold-issues#2-III-B-2)** is an individual or entity having the authority to act on behalf of, or at the direction of, the employer.

The ADA generally restricts when employers may require medical examinations (procedures or tests that seek information about an individual's physical or mental impairments or health) or make disability-related inquiries (questions that are likely to elicit information about an individual's disability). The act of administering the vaccine is not a "medical examination" under the ADA because it does not seek information about the employee's physical or mental health.

However, because the pre-vaccination screening questions are likely to elicit information about a disability, the ADA requires that they must be "job related and consistent with business necessity" when an employer or its agent administers the COVID-19 vaccine. To meet this standard, an employer would need to have a reasonable belief, based on objective evidence, that an employee who does not answer the questions and, therefore, cannot be vaccinated, will pose a direct threat to the employee's own health or safety or to the

health and safety of others in the workplace. (See general discussion in **Question K.5**.) Therefore, when an employer requires that employees be vaccinated by the employer or its agent, the employer should be aware that an employee may challenge the mandatory pre-vaccination inquiries, and an employer would have to justify them under the ADA.

The ADA also requires employers to keep any employee medical information obtained in the course of an employer vaccination program confidential.

Voluntary Employer Vaccination Programs

K.8. Under the ADA, are there circumstances in which an employer or its agent may ask disability-related screening questions before administering a COVID-19 vaccine *without* needing to satisfy the "job-related and consistent with business necessity" standard? *(12/16/20, updated 5/28/21)*

Yes. If the employer offers to vaccinate its employees on a voluntary basis, meaning that employees can choose whether or not to get the COVID-19 vaccine from the employer or its agent, the employer does not have to show that the pre-vaccination screening questions are job-related and consistent with business necessity. However, the employee's decision to answer the questions must be voluntary. (See also Questions **K.16 – 17**.) The ADA prohibits taking an adverse action against an employee, including harassing the employee, for refusing to participate in a voluntary employer-administered vaccination program. An employer also must keep any medical information it obtains from any voluntary vaccination program confidential.

K.9. Under the ADA, is it a "disability-related inquiry" for an employer to inquire about or request documentation or other confirmation that an employee obtained the COVID-19 vaccine from a third party in the community, such as a pharmacy, personal health care provider, or public clinic? *(12/16/20, updated 5/28/21)*

No. When an employer asks employees whether they obtained a COVID-19 vaccine from a third party in the community, such as a pharmacy, personal health care provider, or public clinic, the employer is not asking a question that is likely to disclose the existence of a disability; there are many reasons an employee may not show documentation or other confirmation of vaccination in the community besides having a disability. Therefore, requesting documentation or other confirmation of vaccination by a third party in the community is not a disability-related inquiry under the ADA, and the ADA's rules about such inquiries do not apply.

However, documentation or other confirmation of vaccination provided by the employee to the employer is medical information about the employee and must be kept confidential.

K.10. May an employer offer voluntary vaccinations only to certain groups of employees? *(5/28/21)*

If an employer or its agent offers voluntary vaccinations to employees, the employer must comply with federal employment nondiscrimination laws. For example, not offering voluntary vaccinations to certain employees based on national origin or another protected basis under the EEO laws would not be permissible.

K.11. What should an employer do if an employee who is fully vaccinated for COVID-19 requests accommodation for an underlying disability because of a continuing concern that he or she faces a heightened risk of severe illness from a COVID-19 infection, despite being vaccinated? *(5/28/21)*

spread of COVID-19 and issued attendant precautions, employers may measure employees' body temperature. However, employers should be aware that some people with COVID-19 do not have a fever.

A.4. Does the ADA allow employers to require employees to stay home if they have symptoms of the COVID-19? *(3/17/20)*

Yes. The CDC states that employees who become ill with symptoms of COVID-19 should leave the workplace. The ADA does not interfere with employers following this advice.

A.5. When employees return to work, does the ADA allow employers to require a doctor's note certifying fitness for duty? *(3/17/20)*

Yes. Such inquiries are permitted under the ADA either because they would not be disability-related or, if the pandemic were truly severe, they would be justified under the ADA standards for disability-related inquiries of employees. As a practical matter, however, doctors and other health care professionals may be too busy during and immediately after a pandemic outbreak to provide fitness-for-duty documentation. Therefore, new approaches may be necessary, such as reliance on local clinics to provide a form, a stamp, or an e-mail to certify that an individual does not have the pandemic virus.

A.6. May an employer administer a COVID-19 test (a test to detect the presence of the COVID-19 virus) when evaluating an employee's initial or continued presence in the workplace? *(4/23/20; updated 9/8/20 to address stakeholder questions about updates to CDC guidance)*

The ADA requires that any mandatory medical test of employees be "job related and consistent with business necessity." Applying this standard to the current circumstances of the COVID-19 pandemic, employers may take screening steps to determine if **employees entering the workplace have COVID-19 (https://www.eeoc.gov/web/20211231162411/https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws#A.2)** because **an individual with the virus will pose a direct threat**

(https://www.eeoc.gov/web/20211231162411/https://www.eeoc.gov/transcript-march-27-2020-outreach-webinar#q1) to the health of others. Therefore an employer may choose to administer COVID-19 testing to employees before initially permitting them to enter the workplace and/or periodically to determine if their presence in the workplace poses a direct threat to others. The ADA does not interfere with employers following **recommendations by the CDC (https://web.archive.org/web/20211231162411/https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html)** or other public health authorities regarding whether, when, and for whom testing or other screening is appropriate. Testing administered by employers consistent with current CDC guidance will meet the ADA's "business necessity" standard.

Consistent with the ADA standard, employers should ensure that the tests are considered accurate and reliable. For example, employers may review **information (https://web.archive.org/web/20211231162411/https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)** from the U.S. Food and Drug Administration about what may or may not be considered safe and accurate testing, as well as guidance from CDC or other public health authorities. Because the CDC and FDA may revise their recommendations based on new information, it may be helpful to check these agency websites for updates. Employers may wish to consider the incidence of false-positives or false-negatives associated with a particular test. Note that a positive test result reveals that an individual most likely has a current infection and may be able to transmit the virus to others. A negative test result means that the individual did not have detectable COVID-19 at the time of testing.

A negative test does not mean the employee will not acquire the virus later. Based on guidance from medical and public health authorities, employers should still require–to the greatest extent possible–that employees observe infection control practices (such as social distancing, regular handwashing, and other measures) in the workplace to prevent transmission of COVID-19.

Other federal laws, as well as state or local laws, may provide employees with additional protections.

- Title I of the ADA applies to private employers with 15 or more employees. It also applies to state and local government employers, employment agencies, and labor unions. All nondiscrimination standards under Title I of the ADA also apply to federal agencies under Section 501 of the Rehabilitation Act. Basic background information about the ADA and the Rehabilitation Act is available on EEOC's **disability page (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/disability-discrimination)** .

- The EEO laws, including Title I of the ADA and the Rehabilitation Act, continue to apply during the time of the COVID-19 pandemic, but they do not interfere with or prevent employers from following current guidance and suggestions made by CDC or state/local public health authorities about steps employers should take regarding COVID-19.

- The EEOC has provided guidance (a publication entitled **Pandemic Preparedness in the Workplace and the Americans With Disabilities Act (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act)** [**PDF version (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/sites/default/files/2020-04/pandemic_flu.pdf)**]) ("Pandemic Preparedness"), consistent with these workplace protections and rules, that can help employers implement strategies to navigate the impact of COVID-19 in the workplace. This pandemic publication, which was written during the prior H1N1 outbreak, is still relevant today and identifies established ADA and Rehabilitation Act principles to answer questions frequently asked about the workplace during a pandemic. It has been updated as of March 19, 2020 to address examples and information regarding COVID-19; **the new 2020 information appears in bold and is marked with an asterisk**.

- On March 27, 2020 the EEOC provided a webinar ("3/27/20 Webinar") which was recorded and transcribed and is available at **www.eeoc.gov/coronavirus (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/coronavirus)** . The World Health Organization (WHO) has declared COVID-19 to be an international pandemic. The EEOC pandemic publication includes a **separate section (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/laws/guidance/pandemic-preparedness-workplace-and-americans-disabilities-act#secB)** that answers common employer questions about what to do after a pandemic has been declared.

A. Disability-Related Inquiries and Medical Exams

The ADA has restrictions on when and how much medical information an employer may obtain from any applicant or employee.

Prior to making a conditional job offer to an applicant, disability-related inquiries and medical exams are generally prohibited. They are permitted between the time of the offer and when the applicant begins work, provided they are required for everyone in the same job category. For more information on the timing of disability-related inquiries and medical examinations for applicants, see ***Section C.***

Under the ADA (which is applicable to the Federal sector through the Rehabilitation Act of 1973), once an employee begins work, any disability-related inquiries or medical exams must be "job-related and consistent with business necessity." One way inquiries and medical examinations meet this "business necessity" standard is if they are necessary to determine whether a specific employee has a medical condition that would pose a "direct threat" to health or safety (a significant risk of substantial harm to self or others that cannot be addressed with reasonable accommodation). For more information on reasonable accommodation, see ***Section D****. Where met, the "business necessity" standard allows for consideration of whether a person may have COVID-19,*

and thus might pose a "direct threat." For information on disability-related questions and COVID-19 vaccinations, see ***K.7.*** *-* ***K.9.***

CDC has updated its guidance (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance.html) *over the course of the pandemic and may continue to do so as the pandemic evolves and as CDC acquires more information about the virus and different variants. The ADA "business necessity" standard requires that employers utilize the most current medical and public health information to determine what inquiries/medical examinations are appropriate.*

A.1. How much information may an employer request from an employee who calls in sick, in order to protect the rest of its workforce during the COVID-19 pandemic? *(3/17/20)*

During a pandemic, ADA-covered employers may ask such employees if they are experiencing symptoms of the pandemic virus. For COVID-19, these include symptoms such as fever, chills, cough, shortness of breath, or sore throat. Employers must maintain all information about employee illness as a confidential medical record in compliance with the ADA.

A.2. When screening employees entering the workplace during this time, may an employer only ask employees about the COVID-19 symptoms EEOC has identified as examples (https://www.eeoc.gov/web/20220714153903/https://www.eeoc.gov/transcript-march-27-2020-outreach-webinar#q1) , or may it ask about any symptoms identified by public health authorities as associated with COVID-19? *(4/9/20)*

As public health authorities and doctors learn more about COVID-19, they may expand the list of associated symptoms. Employers should rely on the CDC, other public health authorities, and reputable medical sources for guidance on emerging symptoms associated with the disease. These sources may guide employers when choosing questions to ask employees to determine whether they would pose a direct threat to health in the workplace. For example, additional symptoms beyond fever or

cough may include new loss of smell or taste as well as gastrointestinal problems, such as nausea, diarrhea, and vomiting.

A.3. When may an ADA-covered employer take the body temperature of employees during the COVID-19 pandemic? *(3/17/20)*

Generally, measuring an employee's body temperature is a medical examination. Because the CDC and state/local health authorities have acknowledged community spread of COVID-19 and issued attendant precautions, employers may measure employees' body temperature. However, employers should be aware that some people with COVID-19 do not have a fever.

A.4. Does the ADA allow employers to require employees to stay home if they have symptoms of the COVID-19? *(3/17/20)*

Yes. The CDC states that employees who become ill with symptoms of COVID-19 should leave the workplace. The ADA does not interfere with employers following this advice.

A.5. When an employee returns to the workplace after being out with COVID-19, does the ADA allow employers to require a note from a qualified medical professional explaining that it is safe for the employee to return (i.e., no risk of transmission) and that the employee is able to perform the job duties? *(Updated 7/12/22)*

Yes. Alternatively, employers may follow **CDC guidance (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html)** to determine whether it is safe to allow an employee to return to the workplace without confirmation from a medical professional.

When an employee returns to the workplace after being out with COVID-19, the ADA allows an employer to require confirmation from a qualified medical professional explaining that the individual is able to safely return. Such a request is permitted under the ADA. First, because COVID-19 is not always a disability, a request for confirmation may not be a disability-related inquiry. Alternatively, if the request is

considered a **disability-related inquiry**, it would be justified under the ADA standard requiring that such employee inquiries be job-related and consistent with business necessity. Here, the request meets the "business necessity" standard because it is related to the possibility of transmission and/or related to an employer's objective concern about the employee's ability to resume working. For example, an employer may require confirmation from a medical professional addressing whether an employee may resume specific job duties requiring physical exertion.

As a practical matter, employers may wish to consider other ways to determine the safety of allowing an employee to return to work if doctors and other healthcare professionals are unable to provide such documentation either in a timely manner or at all. This might include reliance on local clinics to provide a form, a stamp, or an e-mail to confirm that an individual is no longer infectious and is able to resume working.

A.6. Under the ADA, may an employer, as a mandatory screening measure, administer a COVID-19 viral test (a test to detect the presence of the COVID-19 virus) when evaluating an employee's initial or continued presence in the workplace? *(Updated 7/12/22)*

Yes, if the employer can show it is job-related and consistent with business necessity.

A COVID-19 **viral test (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html)** is a medical examination within the meaning of the ADA. Therefore, if an employer implements screening protocols that include COVID-19 viral testing, the ADA requires that any mandatory medical test of employees be "job-related and consistent with business necessity." Employer use of a COVID-19 viral test to screen employees who are or will be in the workplace will meet the "business necessity" standard when it is consistent with guidance from Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and/or state/local public health authorities that is current at the time of testing. Be aware that CDC and other public health authorities periodically update and revise their recommendations about COVID-19 testing, and FDA may revise its

guidance or emergency use authorizations, based on new information and changing conditions.

A **positive** viral test result means that the test detected SARS-CoV-2, the virus that causes COVID-19, at the time of testing, and that the individual most likely has a current infection and may be able to transmit the virus to others. A **negative** test result means the test did not detect SARS-CoV-2 at the time of testing. However, a negative test does not mean the employee does not have any virus, or will not later get the virus. It means only that the virus causing SARS-CoV-2 was not detected by the test.

If an employer seeks to implement screening testing for employees such testing must meet the "business necessity" standard based on relevant facts. Possible considerations in making the "business necessity" assessment may include the **level of community transmission (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/science/community-levels.html)** , the **vaccination status of employees (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html)** , the accuracy and speed of processing for different types of COVID-19 viral tests, the **degree to which breakthrough (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html) infections are possible for employees who are "up to date" on vaccinations (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html)** , t**he ease of transmissibility of the current variant(s), the possible severity of illness from the current variant (https://web.archive.org/web/20220714153903/https://www.cdc.gov/coronavirus/2019-ncov/variants/about-variants.html)** , what types of contacts employees may have with others in the workplace or elsewhere that they are required to work (e.g., working with medically vulnerable individuals), and the potential impact on operations if an employee enters the workplace with COVID-19. In making these assessments, employers should check the latest **CDC guidance**

The Wayback Machine - https://web.archive.org/web/20210801174518/https://www.saferfederalworkforce.g…
An official website of the United States government Here's how you know

Testing

NEW **Q: Can an agency establish a testing program utilizing a third party?**

A: Agencies must establish a testing program. In lieu of conducting testing onsite, agencies can require Federal employees and onsite contractors who are not fully vaccinated or who decline to attest to their vaccination status to provide proof of a timely negative COVID-19 test.

Find COVID-19
Vaccines Near You

Visit Vaccines.gov

Or Call 1-800-232-0233

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For questions or comments, email the Safer Federal Workforce Task Force at SaferFederalWorkforce@gsa.gov

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Testing

NEW **Q: Are agencies required to establish a screening testing program for SARS-CoV-2, the virus that causes COVID-19?**

A: Agencies must establish a screening testing program for SARS-CoV-2, the virus that causes COVID-19, to test federal employees and contractor employees who work onsite and who are not fully vaccinated or who have declined to provide their vaccination information. Enrollment in this testing program is mandatory for those individuals and they must be tested at least once a week. Screening tests are intended to identify asymptomatic or presymptomatic infected individuals without known or suspected exposure to SARS-CoV-2. Both federal employees and contractor employees who are fully vaccinated generally do not need to undergo screening testing.

Agencies may satisfy the requirement to establish a screening testing program in a variety of ways, including through in-house capabilities, a contract with one or more third party testing provider(s), an interagency agreement with another agency that has testing capabilities, or a multi-agency contract.

NEW **Q: What steps may an agency take if a federal employee refuses to take a test?**

A: Refusals to take a test may result in disciplinary measures. In addition to pursuing any disciplinary action, an agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary or other action the agency may pursue. Any decision to bar the employee should occur in consultation with the agency's onsite security authority, agency's human resources office, and agency's legal counsel. If the agency bars the employee from the workplace, and the nature of the employee's work does not allow for it to be performed outside of the workplace, the employee must be placed on paid administrative leave until the question of disciplinary action is resolved. In pursuing an adverse action, the agency must also follow normal processes to provide the required notice to the employee.

However, if an employee raises a disability or religious issue as the reason for not being tested, an agency should follow its process to review and consider what, if any, reasonable accommodation should be offered. All agency personnel designated to receive requests for disability

accommodations should also know how to handle requests consistent with other federal employment nondiscrimination laws that may apply—for instance, with respect to religious accommodations. While the request is being resolved, the agency may bar the employee from official worksites. During that temporary period, the agency may direct the employee to work from home. If the employee's duties cannot be performed via telework, the employee should be granted administrative leave.

If the employee's request for an accommodation is denied, and the employee does not comply with the testing requirement, the agency may pursue disciplinary action.

NEW **Q: Are agencies required to pay for the cost of testing employees pursuant to their screening testing program?**

A: Yes, agencies are required to pay for the cost of testing federal employees pursuant to their screening testing program. Agencies are also responsible for paying the cost of testing should an employee visit another federal agency if the employee's agency has approved the visit in advance.

NEW **Q: What types of test may an agency utilize for its testing program?**

A: Agencies may utilize any COVID-19 viral test, such as a PCR or antigen test, that has been authorized by the Food and Drug Administration to detect current infection. Any test that an agency utilizes must include a report that documents the test result and can be provided to the federal employee or contractor employee who was tested, the agency, or both. If the results are provided to the federal employee or contractor employee who was tested, the agency must establish a means for the federal employee or contractor employee to provide those results to the appropriate agency staff for verification that required testing has been completed. If the results are provided directly to the employer, the report should be provided in compliance with regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended.

NEW **Q: Can agencies utilize pooled specimen testing in their testing program?**

A: Yes, agencies can utilize pooled specimen testing, assuming the testing program utilizes any COVID-19 viral test that is used to detect current infection and has been authorized by the Food and Drug Administration, and provides results to the employee, the agency, or both. Pooled specimen testing combines the same type of specimen from several people and conducts one test on the combined specimen. If the pooled specimen test returns a positive result, each specimen in the pool must be retested individually.

NEW **Q: Does the testing requirement apply to not fully vaccinated federal employees and contractor employees who are not reporting to their worksite (e.g., are on maximum telework or working remotely)?**

A: No, only those federal employees and contractor employees who are not fully vaccinated or decline to provide their vaccination status and who work onsite are required to undergo regular testing.

If an employee who is not fully vaccinated or declines to provide their vaccination status does not report to a worksite during a particular week (e.g., due to taking leave or teleworking), they do not need to be tested that week.

NEW **Q: Can an agency require a federal employee who is not fully vaccinated or who has declined to provide their vaccination information to work remotely or telework, solely on the basis of their vaccination status and in lieu of entering that individual into a testing program?**

A: No, an agency may not require a federal employee who is not fully vaccinated to work from home based solely on their vaccination status.

NEW **Q: Does the testing requirement apply to federal employees and onsite contractor employees who only work onsite on an infrequent basis?**

A: Federal employees and contractor employees who are not fully vaccinated or who have declined to provide their vaccination information and who work onsite on an infrequent basis must be tested at least once in any week that they are working onsite.

NEW **Q: Should agencies allow employees to undertake required testing on duty time?**

A: Yes. When a federal employee is required to be tested pursuant to an agency's testing program, the time the employee spends obtaining the test (including travel time) from a site preapproved by the agency is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. An agency should only authorize an employee to spend time obtaining a test during the employee's basic tour of duty hours and only for the amount of time necessary to obtain the test. In most circumstances, agencies should authorize employees to take no more than one hour to travel to the testing site, complete testing, and return to work. Agencies should require employees taking longer than one hour to document the reasons for the additional time. If, due to unforeseen circumstances, the employee is unable to obtain the test during basic tour of duty hours, the normal overtime hours of work rules apply.

Reasonable travel costs that are incurred as a result of obtaining the test from a site preapproved by the agency should be handled the same way as local travel or temporary duty (TDY) cost reimbursement is handled based on agency policy.

When an employee is not required to be tested but decides to obtain a COVID-19 test during basic tour of duty hours at the employee's own initiative, the employee may request sick leave or other

available paid time off for that situation.

NEW **Q: Are federal employees and contractor employees participating in an agency testing program limited in their ability to work onsite in between weekly tests?**

A: No, provided that they have met any applicable testing requirement and have not tested positive for COVID-19, federal employees and contractor employees participating in an agency testing program are not limited in their ability to work onsite between weekly tests, although they must comply with all relevant safety protocols for not fully vaccinated individuals. However, if the employee or contractor employee has come into close contact with a person with COVID-19 during this time, they should follow CDC guidelines for testing and quarantine and not enter a worksite. Similarly, if they have symptoms consistent with COVID-19, they should not enter a worksite.

Agencies should develop a procedure for addressing circumstances in which employees or onsite contractor employees miss their regular testing requirement, which may include restricting the individual's access to worksites if they have not obtained a test within a period of time specified by the agency.

An employee's failure to comply with testing requirements can result in discipline, including an adverse action. An agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary action. A contractor employee's failure to comply with testing requirements can have consequences such as removal from the contract for the convenience of the Government.

NEW **Q: What steps should an agency consider in determining the frequency of required testing for employees and onsite contractor employees in specific workplaces?**

A: Federal employees and contractor employees who work onsite and who are not fully vaccinated or who have declined to provide their vaccination information must be tested at least once a week. As set forth by the Centers for Disease Control and Prevention in its testing guidance for federal workers, agencies should consider workplace characteristics, availability of testing, cost, and level of community transmission, among other factors in determining the frequency of required testing for federal employees and onsite contractor employees. Agencies may have different testing frequency for employees with different job responsibilities or worksites. Generally, agencies should not need to test federal employees and onsite contractor employees more than twice a week.

NEW **Q: Can information on employee and contractor employee test results be stored by an agency? How must information on test results be stored? How long must the information be stored for and who may have access to it?**

A: Agencies have unique operational environments and may develop their own processes to document COVID-19 test results in compliance with all applicable laws and in accordance with their agency's records management policies.

The Privacy Act statement for the testing requirements will refer to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). Under those rules, each agency must have written instructions for its EMF system with appropriate safeguards, and must retain short-term medical records under the applicable record schedule. Agencies with positions that are not subject to OPM's regulations or that are not subject to OPM/GOVT-10 must give their employees an alternative Privacy Act statement. Any COVID-19 related certification or vaccination information must be maintained separately from the Official Personnel Folder. The Rehabilitation Act also requires that test results be kept confidential and limits who may have access to such information. Agencies are encouraged to take steps to promote privacy and IT security, while also providing the relevant information to agency officials who need to know in order to implement the safety protocols.

Agencies should consult, as appropriate, with their Agency Records Officer, Chief Information Officer, Chief Medical Officer, Senior Agency Official for Privacy, and agency legal counsel to determine appropriate information management protocols.

NEW **Q: Are agencies required to provide testing for work-related exposures?**

A: Federal employees who have been exposed to persons with COVID-19 at work should receive diagnostic testing. Agencies that have in-house capabilities (either through an occupational health clinic or through the utilization of contract options) can provide testing at the worksite; if an agency does not provide testing at the worksite, it should determine a process for employee diagnostic testing.

NEW **Q: Can an employee get reimbursed for costs related to testing if required for official travel?**

A: Yes, the cost of testing for current infection with SARS-CoV-2, required for official travel and not available through a federal dispensary or not covered (or reimbursable) through travel insurance, can be claimed in a travel voucher as a Miscellaneous Expense under agency travel policies.

NEW **Q: Does the employee have a responsibility to pay for their own testing if the exposure is not work-related?**

A: An agency is not responsible for providing testing to an individual as a result of a potential exposure that is not work-related. If the employee or contractor employee has come into close

contact with a person with COVID-19 outside of work, they should follow CDC guidelines for testing and quarantine and not enter a worksite.

NEW **Q: If an employee tests positive for SARS-CoV-2 infection, is the agency required to record the COVID-19 case on the OSHA Injury and Illness Log?**

A: Under OSHA's recordkeeping requirements, if an employee tests positive for SARS-CoV-2 infection, the case must be recorded on the OSHA Illness and Injury Log if each of the following conditions are met: (1) the case is a confirmed case of COVID-19; (2) the case is work-related (as defined by 29 CFR 1904.5); and (3) the case involves one or more relevant recording criteria (set forth in 29 CFR 1904.7) (e.g., medical treatment beyond first aid, days away from work). Employers should also follow state and county reporting requirements and comply with state and county contact tracing efforts.

NEW **Q: Should agencies discuss testing plans with their employee unions?**

A: Since agencies need to act quickly due to the COVID-19 emergency and to protect the health and safety of onsite employees, contractor employees, and visitors, agencies should engage with employee unions at their earliest opportunity as they develop agency-specific testing plans and otherwise satisfy any applicable collective bargaining obligations under the law at the earliest opportunity, including on a post-implementation basis where appropriate.

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An official website of the United States government Here's how you know

Testing

Q: Are agencies required to establish a screening testing program for SARS-CoV-2, the virus that causes COVID-19?

A: No, though an agency may decide to establish its own screening testing program.

Q: If an agency decides to establish a screening testing program, what steps may it take if a federal employee refuses to take a COVID-19 test required pursuant to that program?

A: Refusals to take a required test may result in disciplinary measures. In addition to pursuing any disciplinary action, an agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary or other action the agency may pursue. Any decision to bar the employee should occur in consultation with the agency's onsite security authority, agency's human resources office, and agency's legal counsel. If the agency bars the employee from the workplace, and the nature of the employee's work does not allow for it to be performed outside of the workplace, the employee must be placed on paid administrative leave until the question of disciplinary action is resolved. In pursuing an adverse action, the agency must also follow normal processes to provide the required notice to the employee.

An agency follows a different process if the employee seeks a reasonable accommodation. In that case, an agency should follow its ordinary process to review and consider what, if any, reasonable accommodation should be offered. All agency personnel designated to receive requests for disability accommodations should also know how to handle requests consistent with other federal employment nondiscrimination laws that may apply. While the request is being resolved, the agency may bar the employee from official worksites. During that temporary period, the agency may direct the employee to work from home. If the employee's duties cannot be performed via telework, the employee should be granted administrative leave.

If the employee's request for an accommodation is denied, and the employee does not comply with a testing requirement, the agency may pursue disciplinary action.

Q: Are agencies required to pay for the cost of testing employees pursuant to a screening testing program?

A: Yes, agencies that establish a screening testing program are required to pay for the cost of testing federal employees pursuant to that program. Agencies are also responsible for paying the cost of testing should an employee visit another federal agency if the employee's agency has approved the visit in advance.

Q: What types of test may an agency utilize for a screening testing program?

A: Agencies may utilize any COVID-19 viral test, such as a PCR or antigen test, that has been authorized by the Food and Drug Administration to detect current infection. If the results are provided to the federal employee or contractor employee who was tested, the agency must establish a means for the federal employee or contractor employee to provide those results to the appropriate agency staff for verification that required testing has been completed. If the results are provided directly to the employer, the report should be provided in compliance with regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended.

Q: Can agencies utilize pooled specimen testing in a testing program?

A: Yes, agencies can utilize pooled specimen testing, assuming the testing program utilizes any COVID-19 viral test that is used to detect current infection and has been authorized by the Food and Drug Administration. Pooled specimen testing combines the same type of specimen from several people and conducts one test on the combined specimen. If the pooled specimen test returns a positive result, each specimen in the pool must be retested individually.

Q: Should agencies allow employees to undertake any required testing on duty time?

A: Yes. When a federal employee is required to be tested pursuant to an agency's testing program, the time the employee spends obtaining the test (including travel time) from a site preapproved by the agency is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. An agency should only authorize an employee to spend time obtaining a test during the employee's basic tour of duty hours and only for the amount of time necessary to obtain the test. In most circumstances, agencies should authorize employees to take no more than one hour to travel to the testing site, complete testing, and return to work. Agencies should require employees taking longer than one hour to document the reasons for the additional time. If, due to unforeseen circumstances, the employee is unable to obtain the test during basic tour of duty hours, the normal overtime hours of work rules apply.

Reasonable travel costs that are incurred as a result of obtaining the test from a site preapproved by the agency should be handled the same way as local travel or temporary duty (TDY) cost

reimbursement is handled based on agency policy and the Federal Travel Regulation.

When an employee is not required to be tested but decides to obtain a COVID-19 test during basic tour of duty hours at the employee's own initiative, the employee may request sick leave or other available paid time off for that situation.

Q: Are federal employees and contractor employees participating in an agency testing program limited in their ability to work onsite in between tests?

A: No, provided that they have met any applicable testing requirement and have not tested positive for COVID-19, federal employees and contractor employees participating in an agency testing program are not limited in their ability to work onsite between tests, although they must comply with all relevant safety protocols. However, if the employee or contractor employee has come into close contact with a person with COVID-19 during this time, they should follow CDC guidelines for testing and quarantine and not enter a worksite. Similarly, if they have symptoms consistent with COVID-19, they should not enter a worksite.

Agencies should develop a procedure for addressing circumstances in which employees or onsite contractor employees miss their required test, which may include restricting the individual's access to worksites if they have not obtained a test within a period of time specified by the agency.

An employee's failure to comply with testing requirements can result in discipline, including an adverse action. An agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary action. A contractor employee's failure to comply with testing requirements may result in that individual being denied entry to a federal building. Such circumstances do not relieve the contractor from meeting all contractual requirements.

Q: Can information on employee test results be stored by an agency? How must information on test results be stored? How long must the information be stored for and who may have access to it?

A: Agencies have unique operational environments and may develop their own processes to document COVID-19 test results in compliance with all applicable laws and in accordance with their agency's records management policies.

The Privacy Act statement for the testing requirements will refer to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). Under those rules, each agency must have written instructions for its EMF system with appropriate safeguards, and must retain short-term medical records under the applicable record schedule. Agencies with positions that are not subject to OPM's regulations or that

are not subject to OPM/GOVT-10 must give their employees an alternative Privacy Act statement. Any COVID-19 related certification or vaccination information must be maintained separately from the Official Personnel Folder. The Rehabilitation Act also requires that test results be kept confidential and limits who may have access to such information. Agencies are encouraged to take steps to promote privacy and IT security, while also providing the relevant information to agency officials who need to know in order to implement the safety protocols.

Agencies should consult, as appropriate, with their Agency Records Officer, Chief Information Officer, Chief Medical Officer, Senior Agency Official for Privacy, and agency legal counsel to determine appropriate information management protocols.

Q: Are agencies required to provide testing for work-related exposures?

A: Federal employees who have been exposed to persons with COVID-19 at work should receive diagnostic testing at no cost to the employee. Agencies that have in-house capabilities (either through an occupational health clinic or through the utilization of contract options) can provide testing at the worksite; if an agency does not provide testing at the worksite, it should determine a process for employee diagnostic testing.

Q: Can an employee get reimbursed for costs related to testing if required for official travel?

A: Yes, the cost of testing for current infection with SARS-CoV-2, required for official travel and not available through a federal dispensary or not covered (or reimbursable) through travel insurance, can be claimed in a travel voucher as a Miscellaneous Expense under agency travel policies.

Q: Does the employee have a responsibility to pay for their own testing if the exposure is not work-related?

A: An agency is not responsible for providing testing to an individual as a result of a potential exposure that is not work-related. If the employee or contractor employee has come into close contact with a person with COVID-19 outside of work, they should follow CDC guidelines for testing and quarantine and not enter a worksite.

Q: If an employee tests positive for SARS-CoV-2 infection, is the agency required to record the COVID-19 case on the OSHA Injury and Illness Log?

A: Under OSHA's recordkeeping requirements, if an employee tests positive for SARS-CoV-2 infection, the case must be recorded on the OSHA Illness and Injury Log if each of the following conditions are met: (1) the case is a confirmed case of COVID-19; (2) the case is work-related (as defined by 29 CFR 1904.5); and (3) the case involves one or more relevant recording criteria (set forth in 29 CFR 1904.7)

(e.g., medical treatment beyond first aid, days away from work). Employers should also follow state and county reporting requirements and comply with state and county contact tracing efforts.

Q: Should agencies discuss any testing plans with their employee unions?

A: Agencies should engage with employee unions at their earliest opportunity as they develop any agency-specific testing plans and otherwise satisfy any applicable collective bargaining obligations under the law at the earliest opportunity, including on a post-implementation basis where appropriate.

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Testing

Q: Are agencies required to establish a screening testing program for SARS-CoV-2, the virus that causes COVID-19?

A: No, though an agency may decide to establish its own screening testing program.

Q: If an agency decides to establish a screening testing program, what steps may it take if a federal employee refuses to take a COVID-19 test required pursuant to that program?

A: Refusals to take a required test may result in disciplinary measures. In addition to pursuing any disciplinary action, an agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary or other action the agency may pursue. Any decision to bar the employee should occur in consultation with the agency's onsite security authority, agency's human resources office, and agency's legal counsel. If the agency bars the employee from the workplace, and the nature of the employee's work does not allow for it to be performed outside of the workplace, the employee must be placed on paid administrative leave until the question of disciplinary action is resolved. In pursuing an adverse action, the agency must also follow normal processes to provide the required notice to the employee.

An agency follows a different process if the employee seeks a reasonable accommodation. In that case, an agency should follow its ordinary process to review and consider what, if any, reasonable accommodation should be offered. All agency personnel designated to receive requests for disability accommodations should also know how to handle requests consistent with other federal employment nondiscrimination laws that may apply. While the request is being resolved, the agency may bar the employee from official worksites. During that temporary period, the agency may direct the employee to work from home. If the employee's duties cannot be performed via telework, the employee should be granted administrative leave.

If the employee's request for an accommodation is denied, and the employee does not comply with a testing requirement, the agency may pursue disciplinary action.

Q: Are agencies required to pay for the cost of testing employees pursuant to a screening testing program?

A: Yes, agencies that establish a screening testing program are required to pay for the cost of testing federal employees pursuant to that program. Agencies are also responsible for paying the cost of testing should an employee visit another federal agency if the employee's agency has approved the visit in advance.

Q: What types of test may an agency utilize for a screening testing program?

A: Agencies may utilize any COVID-19 viral test, such as a PCR or antigen test, that has been authorized by the Food and Drug Administration to detect current infection. If the results are provided to the federal employee or contractor employee who was tested, the agency must establish a means for the federal employee or contractor employee to provide those results to the appropriate agency staff for verification that required testing has been completed. If the results are provided directly to the employer, the report should be provided in compliance with regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended.

Q: Can agencies utilize pooled specimen testing in a testing program?

A: Yes, agencies can utilize pooled specimen testing, assuming the testing program utilizes any COVID-19 viral test that is used to detect current infection and has been authorized by the Food and Drug Administration. Pooled specimen testing combines the same type of specimen from several people and conducts one test on the combined specimen. If the pooled specimen test returns a positive result, each specimen in the pool must be retested individually.

Q: Should agencies allow employees to undertake any required testing on duty time?

A: Yes. When a federal employee is required to be tested pursuant to an agency's testing program, the time the employee spends obtaining the test (including travel time) from a site preapproved by the agency is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. An agency should only authorize an employee to spend time obtaining a test during the employee's basic tour of duty hours and only for the amount of time necessary to obtain the test. In most circumstances, agencies should authorize employees to take no more than one hour to travel to the testing site, complete testing, and return to work. Agencies should require employees taking longer than one hour to document the reasons for the additional time. If, due to unforeseen circumstances, the employee is unable to obtain the test during basic tour of duty hours, the normal overtime hours of work rules apply.

Reasonable travel costs that are incurred as a result of obtaining the test from a site preapproved by the agency should be handled the same way as local travel or temporary duty (TDY) cost

reimbursement is handled based on agency policy and the Federal Travel Regulation.

When an employee is not required to be tested but decides to obtain a COVID-19 test during basic tour of duty hours at the employee's own initiative, the employee may request sick leave or other available paid time off for that situation.

Q: Are federal employees and contractor employees participating in an agency testing program limited in their ability to work onsite in between tests?

A: No, provided that they have met any applicable testing requirement and have not tested positive for COVID-19, federal employees and contractor employees participating in an agency testing program are not limited in their ability to work onsite between tests, although they must comply with all relevant safety protocols. However, if the employee or contractor employee has come into close contact with a person with COVID-19 during this time, they should follow CDC guidelines for testing and quarantine and not enter a worksite. Similarly, if they have symptoms consistent with COVID-19, they should not enter a worksite.

Agencies should develop a procedure for addressing circumstances in which employees or onsite contractor employees miss their required test, which may include restricting the individual's access to worksites if they have not obtained a test within a period of time specified by the agency.

An employee's failure to comply with testing requirements can result in discipline, including an adverse action. An agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary action. A contractor employee's failure to comply with testing requirements may result in that individual being denied entry to a federal building. Such circumstances do not relieve the contractor from meeting all contractual requirements.

Q: Can information on employee test results be stored by an agency? How must information on test results be stored? How long must the information be stored for and who may have access to it?

A: Agencies have unique operational environments and may develop their own processes to document COVID-19 test results in compliance with all applicable laws and in accordance with their agency's records management policies.

The Privacy Act statement for the testing requirements will refer to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). Under those rules, each agency must have written instructions for its EMF system with appropriate safeguards, and must retain short-term medical records under the applicable record schedule. Agencies with positions that are not subject to OPM's regulations or that

are not subject to OPM/GOVT-10 must give their employees an alternative Privacy Act statement. Any COVID-19 related certification or vaccination information must be maintained separately from the Official Personnel Folder. The Rehabilitation Act also requires that test results be kept confidential and limits who may have access to such information. Agencies are encouraged to take steps to promote privacy and IT security, while also providing the relevant information to agency officials who need to know in order to implement the safety protocols.

Agencies should consult, as appropriate, with their Agency Records Officer, Chief Information Officer, Chief Medical Officer, Senior Agency Official for Privacy, and agency legal counsel to determine appropriate information management protocols.

Q: Are agencies required to provide testing for work-related exposures?

A: Federal employees who have been exposed to persons with COVID-19 at work should receive diagnostic testing at no cost to the employee. Agencies that have in-house capabilities (either through an occupational health clinic or through the utilization of contract options) can provide testing at the worksite; if an agency does not provide testing at the worksite, it should determine a process for employee diagnostic testing.

Q: Can an employee get reimbursed for costs related to testing if required for official travel?

A: Yes, the cost of testing for current infection with SARS-CoV-2, required for official travel and not available through a federal dispensary or not covered (or reimbursable) through travel insurance, can be claimed in a travel voucher as a Miscellaneous Expense under agency travel policies.

Q: Does the employee have a responsibility to pay for their own testing if the exposure is not work-related?

A: An agency is not responsible for providing testing to an individual as a result of a potential exposure that is not work-related. If the employee or contractor employee has come into close contact with a person with COVID-19 outside of work, they should follow CDC guidelines for testing and quarantine and not enter a worksite.

Q: If an employee tests positive for SARS-CoV-2 infection, is the agency required to record the COVID-19 case on the OSHA Injury and Illness Log?

A: Under OSHA's recordkeeping requirements, if an employee tests positive for SARS-CoV-2 infection, the case must be recorded on the OSHA Illness and Injury Log if each of the following conditions are met: (1) the case is a confirmed case of COVID-19; (2) the case is work-related (as defined by 29 CFR 1904.5); and (3) the case involves one or more relevant recording criteria (set forth in 29 CFR 1904.7)

(e.g., medical treatment beyond first aid, days away from work). Employers should also follow state and county reporting requirements and comply with state and county contact tracing efforts.

Q: Should agencies discuss any testing plans with their employee unions?

A: Agencies should engage with employee unions at their earliest opportunity as they develop any agency-specific testing plans and otherwise satisfy any applicable collective bargaining obligations under the law at the earliest opportunity, including on a post-implementation basis where appropriate.

NEW **Q: When should a fully vaccinated employee or onsite contractor employee be tested after a close contact with someone with suspected or confirmed COVID-19?**

A: Individuals who have been fully vaccinated and have had close contact with someone with suspected or confirmed COVID-19 should get tested 5-7 days after exposure, even if they do not have symptoms. They should also wear a mask indoors in public for 14 days following exposure or until their test result is negative. If their test result is positive, they should isolate for 10 days.



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Testing

Screening Testing NEW AND UPDATED

NEW **Q: What is screening testing?**

A: Screening tests are intended to identify infection with SARS-CoV-2, the virus that causes COVID-19, in unvaccinated people who are asymptomatic and do not have known, suspected, or reported exposure to SARS-CoV-2. Screening helps to identify unknown cases so that measures can be taken to prevent further transmission. Screening testing is separate and distinct from diagnostic testing, which should be performed on anyone that has signs and symptoms consistent with COVID-19 or following recent known or suspected exposure to SARS-CoV-2.

UPDATED **Q: Should agencies establish a screening testing program for SARS-CoV-2, the virus that causes COVID-19?**

A: Yes, agencies should establish a COVID-19 screening testing program by February 15, 2022 for employees who are not fully vaccinated, including due to a pending or approved request for exception or extension from the COVID-19 vaccination requirement for Federal employees. If an agency is engaged in enforcement steps with an employee covered by the vaccination requirement who is not fully vaccinated and who does not have a pending or approved exception or extension request, those employees should also be included in the agency's screening testing program.

An agency generally does not need to include onsite contractor employees or fully vaccinated employees in its screening testing program. For certain roles, functions, or work environments, an agency may determine that it is necessary that certain onsite contractor employees, certain employees regardless of their vaccination status, or certain employees and certain onsite contractor employees regardless of their vaccination status must participate in screening testing, given operational or administrative considerations associated with conducting screening testing for those roles, functions, or work environments.

NEW **Q: What testing protocols should be applied through an agency's screening testing program to employees who are not fully vaccinated?**

A: Employees who are not fully vaccinated and who work onsite should undergo regular screening testing through their agency's screening testing program. This includes employees who do not work at a Federal facility but who interact in person with members of the public as part of their job duties, such as safety inspectors.

For purposes of regularly testing these employees through a screening testing program, an employee enrolled in the program should be tested weekly for any week during which they work onsite or interact in person with members of the public as part of their job duties. Agencies may require more frequent testing, such as for certain roles, functions, or work environments. Testing may be conducted at a Federal facility or offsite as determined by the agency. The test should not be both self-administered and self-read by the employee unless observed by the agency or an authorized telehealth provider.

NEW **Q: Do Federal employees or contractor employees participating in an agency screening testing program need to be able to provide the results of a negative test in order to enter or be present in a Federal facility?**

Federal employees participating in an agency screening testing program do not need to be able to provide the results of a negative test each time they enter or are present in their agency's facilities, unless required as part of the agency's screening testing program and workplace safety protocols. That said, Federal employees generally are treated as visitors during a visit to another agency, so while they are onsite at *another* agency's worksite, they should be able to show proof of a negative COVID-19 test result administered within the past 3 days, if they are not fully vaccinated or decline to provide their vaccination information to the host agency.

Similarly, contractor employees participating in an agency testing program do not need to be able to provide the results of a negative test each time they enter or are present at that agency's facilities, unless required as part of the agency's testing program and workplace safety protocols. However, if they are visiting *another* agency's facilities, they should be able to show proof of a negative COVID-19 test result administered within the past 3 days, if they are not fully vaccinated or decline to provide their vaccination information to the host agency.

NEW **Q: Do the screening testing protocols apply to employees who are not fully vaccinated and who are not reporting to their worksite (e.g., are on maximum telework, working remotely, or on leave)?**

A: No, employees who are working remotely or who are on maximum telework do not need to undergo regular testing. An employee who does not report to a worksite or interact in person with members of the public as part of their job duties during a particular week (e.g., due to taking leave, teleworking, or working remotely) does not need to be tested that week.

Should these employees have a one-time need to report to one of their agency's facilities, they should be tested in the week they are entering the facility. Should these employees need to be onsite at another agency's facility, they generally would be treated as visitors during their visit, and so should be able to show proof of a negative COVID-19 test result administered within the past 3 days.

NEW **Q: Do the screening testing protocols apply to Federal employees who are not fully vaccinated and who only work onsite on an infrequent basis?**

A: Federal employees who are not fully vaccinated and who work onsite or interact in person with members of the public as part of their job duties on an infrequent basis should be tested at least once in the week that they are working onsite or interact in person with members of the public as part of their job duties. An agency may determine that some employees who generally do not report to a worksite or interact with members of the public as part of their job duties, but may need to do so on an emergency basis (e.g., for accident investigations or disaster response) are required to undergo regular testing on a frequency determined by the agency.

Should these Federal employees need to be onsite at another agency's facility, they generally would be treated as visitors during their visit, and so would need to be able to show proof of a negative COVID-19 test result administered within the past 3 days.

UPDATED **Q: What types of tests may an agency utilize for a screening testing program?**

A: For screening testing programs, agencies may utilize any viral tests authorized by the Food and Drug Administration (FDA) to detect current infection. There are two types of viral tests: antigen tests and nucleic acid application tests (NAATs). Reverse transcriptase polymerase chain reaction (RT-PCR) tests are a type of NAAT. Agencies should consult FDA guidance for specific authorized tests impacted by COVID-19 variants and the current status on recommended use.

Options for testing methods include: (1) in-store or drive-through point-of-care (POC) testing, such as at pharmacies, (2) swab-testing capabilities that enable an individual to collect the specimen—using a self-collection kit—and drop it off at a designated collection location or ship it to a laboratory, (3) over-the-counter (OTC) tests, as long as those tests are not both self-

administered and self-read by the employee unless observed by the agency or an authorized telehealth provider, or (4) other self-administered tests, as long as those tests are not also self-read by the employee unless observed by the agency or an authorized telehealth provider.

Agencies should establish a means of verifying the date and result of a test—the test should not be both self-administered and self-read by the employee unless observed by the agency or an authorized onsite or telehealth provider. If the results are provided to the Federal employee or contractor employee who was tested, the agency should establish a means for the Federal employee or contractor employee to provide those results to the appropriate agency staff for verification that required testing has been completed and the employee has tested negative. Agencies must comply with applicable privacy safeguards and regulations when receiving test results.

UPDATED **Q: What steps may an agency take if a Federal employee refuses to take a COVID-19 test required pursuant to that program?**

A: Refusals to take a required test or to provide the results of the test may result in disciplinary measures. In addition to pursuing any disciplinary action, an agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary or other action the agency may pursue. Any decision to bar the employee should occur in consultation with the agency's onsite security authority, agency's human resources office, and agency's legal counsel. If the agency bars the employee from the workplace, and the nature of the employee's work does not allow for it to be performed outside of the workplace, the employee must be placed on paid administrative leave until the question of disciplinary action is resolved. In pursuing an adverse action, the agency must also follow normal processes to provide the required notice to the employee.

An agency follows a different process if the employee seeks an accommodation from the requirement to be regularly tested. In that case, an agency should follow its ordinary process to review and consider what, if any, accommodation should be offered in accordance with Federal employment nondiscrimination laws. All agency personnel designated to receive requests for disability accommodations should also know how to handle requests consistent with other Federal employment nondiscrimination laws that may apply. While the request is being resolved, the agency may bar the employee from official worksites. During that temporary period, the agency may direct the employee to work from home. If the employee's duties cannot be performed via telework, the employee should be granted administrative leave for the temporary period of time while the request is being resolved.

If the employee's request for an accommodation to a testing requirement is denied, and the employee does not comply with the testing requirement, the agency may pursue disciplinary

action up to and including removal.

UPDATED **Q: Are agencies required to pay for the cost of testing employees pursuant to a screening testing program?**

A: Yes, agencies are required to pay for the cost of screening testing of Federal employees pursuant to the agency's screening testing program. Agencies are also responsible for paying the cost of required testing should an employee visit another Federal agency if the employee's agency has approved the visit in advance. Agencies can either pay for the testing directly or reimburse employees for required tests. Should agencies have questions regarding their approach to funding this testing from agency appropriations, they should contact their respective OMB Resource Management Office.

UPDATED **Q: Can agencies utilize pooled specimen testing in a screening testing program?**

A: Yes, agencies can utilize pooled specimen testing, assuming the screening testing program utilizes any COVID-19 viral test that is used to detect current infection and has been authorized by the Food and Drug Administration for use in pooled testing. Agencies should consult FDA guidance for specific authorized tests impacted by COVID-19 variants and the current status on recommended use.

Pooled specimen testing combines the same type of specimen from several people and conducts one NAAT laboratory test on the combined specimen. If the pooled specimen test returns a positive result, each specimen in the pool must be retested individually. Of note, as the incidence of COVID-19 increases among the population being tested, the cost savings of a pooling strategy decreases because more pooled tests will return positive results, and those specimens will need to be retested individually to determine which individual(s) are positive.

UPDATED **Q: Is required screening testing undertaken on duty time?**

A: Yes. When a Federal employee is required to be tested pursuant to an agency's screening testing program, the time the employee spends obtaining the test (including travel time) from a site preapproved by the agency is duty time; thus, there is no need for the employee to take administrative leave for such time during the employee's basic tour of duty. An agency should only authorize an employee to spend time related to screening testing during the employee's basic tour of duty hours and only for the amount of time necessary. Agencies should determine the amount of time to authorize employees to take to travel to the testing site (if travel is required), complete testing, and return to work. Agencies should require employees taking longer than that amount of time to document the reasons for the additional time. If, due to

unforeseen circumstances, the employee is unable to obtain the test during basic tour of duty hours, the normal overtime hours of work rules apply.

Reasonable travel costs that are incurred as a result of obtaining the test from a site preapproved by the agency should be handled the same way as local travel or temporary duty (TDY) cost reimbursement is handled based on agency policy and the Federal Travel Regulation.

When an employee is not required to be tested but decides to obtain a COVID-19 test during basic tour of duty hours at the employee's own initiative, the employee may request sick leave or other available paid time off for that situation.

UPDATED **Q: Are Federal employees and contractor employees participating in an agency screening testing program limited in their ability to work onsite in between tests?**

A: No, provided that they have met any applicable testing requirement and have not tested positive for COVID-19, Federal employees and contractor employees participating in an agency screening testing program are not limited in their ability to work onsite between tests, although they should comply with all relevant safety protocols. However, if the employee or contractor employee has come into close contact with a person with COVID-19 during this time, they should follow CDC guidelines for testing and quarantine, as well as any other requirements set forth in agency workplace safety protocols. Similarly, if they have symptoms consistent with COVID-19, they should follow agency protocols and not enter a worksite.

Agencies should develop a procedure for addressing circumstances in which employees or onsite contractor employees miss their required test, which may include restricting the individual's access to worksites if they have not obtained a test within a period of time specified by the agency.

An employee's failure to comply with testing requirements can result in disciplinary action, up to and including removal. An agency may separately elect to bar the employee from the agency workplace for the safety of others pending resolution of any disciplinary action. A contractor employee's failure to comply with testing requirements may result in that individual being denied entry to a Federal facility. Such circumstances do not relieve the contractor from meeting all contractual requirements.

Diagnostic Testing NEW AND UPDATED

Testing Results and Information UPDATED

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Vaccinations

NEW Vaccination Status

Q: Should agencies require employees to be vaccinated or inquire regarding their vaccination status?

A: The Administration strongly encourages all Americans, including Federal employees and contractors, to be vaccinated. Employees should receive paid time off to be vaccinated and to deal with any side effects. At present, COVID-19 vaccination should generally not be a pre-condition for employees or contractors at executive departments and agencies (agencies) to work in-person in Federal buildings, on Federal lands, and in other settings as required by their job duties.

Federal employees and contractors may voluntarily share information about their vaccination status, but agencies should not require federal employees or contractors to disclose such information. Responding to agency inquiries should be voluntary, and agencies should comply with any applicable laws, including requirements under the Privacy Act and the Paperwork Reduction Act, and any applicable collective bargaining obligations. When an employee or contractor voluntarily discloses that they are unvaccinated or declines to provide vaccination information, agencies should use that information to implement CDC-recommended mitigation measures, including masking and physical distancing.

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Vaccinations

Vaccination Status

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Federal employees and contractors may voluntarily share information about their vaccination status, but agencies should not require federal employees or contractors to disclose such information. Responding to agency inquiries should be voluntary, and agencies should comply with any applicable laws, including requirements under the Privacy Act and the Paperwork Reduction Act, and any applicable collective bargaining obligations. When an employee or contractor voluntarily discloses that they are unvaccinated or declines to provide vaccination information, agencies should use that information to implement CDC-recommended mitigation measures, including masking and physical distancing.

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Vaccinations

Vaccination Status

NEW **Q: Should agencies inquire regarding the vaccination status of Federal employees and onsite contractors?**

A. Given the different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated, agencies need to ask about the vaccination status of Federal employees and onsite contractors. Employees and onsite contractors must attest to the truthfulness of the response they provide. If an employee or onsite contractor chooses not to provide a response, they will be treated as unvaccinated for the purpose of agency safety protocols. In requesting this information, agencies should comply with any applicable Federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act, and any applicable collective bargaining obligations. When an employee or contractor discloses that they are unvaccinated or declines to complete the attestation, agencies should treat that individual as not fully vaccinated for purposes of implementing safety measures, including with respect to mask wearing, physical distancing, testing, travel, and quarantine.

NEW **Q: Should agencies inquire regarding the vaccination status of visitors to Federal buildings?**

A: Visitors to Federal buildings should be asked to provide information about vaccination status. In requesting this information, agencies should comply with any applicable Federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act. Visitors who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a Federal building.

These requirements related to the provision of information about vaccination and provision of proof of a recent negative COVID-19 test do not apply to members of the public entering a Federal building or Federal land to obtain a public service or benefit. If they are not fully

vaccinated, these visitors must comply with all relevant CDC guidance, including wearing a mask and physically distancing from other people.

NEW **Q: Are agencies required to establish different safety protocols for fully vaccinated and not fully vaccinated individuals?**

A: Yes. Fully vaccinated individuals do not need to physically distance, undergo screening testing, or have restrictions on their official travel (although they still must comply with any local requirements and relevant CDC guidance for fully vaccinated individuals while traveling). Fully vaccinated individuals in areas of substantial or high transmission (see the CDC COVID-19 Data Tracker County View) need to wear a mask in public indoor settings. Fully vaccinated individuals in areas of low or moderate transmission do not need to wear a mask.

Fully vaccinated individuals might choose to wear a mask regardless of the level of transmission for a variety of reasons.

Individuals who are not fully vaccinated or who decline to provide information about their vaccination status must wear masks regardless of community transmission level, physically distance, and undergo screening testing weekly or twice-weekly, and their official travel is restricted.

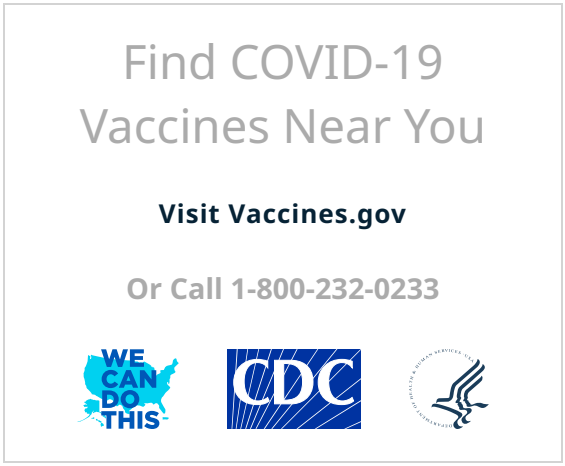
In order to be treated as fully vaccinated pursuant to agency COVID-19 workplace safety plans and protocols, employees and onsite contractors must attest that they are fully vaccinated by signing a form provided by the agency. Visitors also will be asked to provide information about their vaccination status. Individuals who decline to provide information on their vaccination status will be treated as not fully vaccinated for purposes of agency COVID-19 workplace safety plans and protocols. Visitors who are not fully vaccinated must provide proof of a negative COVID-19 test that occurred within the previous 3 days prior to entry to a Federal building.

Individuals entering a Federal building or Federal land to obtain a public service or benefit do not need to provide information about their vaccination status or provide proof of a negative COVID-19 test. If they are not fully vaccinated, they must comply with all relevant CDC guidance, including wearing a mask.

NEW **Q: What safety protocols should an agency apply to employees and onsite contractors prior to establishing a means of determining vaccination status consistent with this guidance?**

A: Agencies may take a reasonable period of time to establish a program for determining the vaccination status of employees and onsite contractors consistent with this guidance. Prior to

an agency establishing such a program, they should continue to utilize their current means of determining the safety protocols that apply to specific employees and contractors.



For questions or comments, email the Safer Federal Workforce Task Force at SaferFederalWorkforce@gsa.gov

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Vaccinations

Vaccination Status

UPDATED **Q: Who is considered fully vaccinated?**

A: People are considered fully vaccinated for COVID-19 ≥2 weeks after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥2 weeks after they have received a single-dose vaccine (Johnson and Johnson (J&J;)/Janssen). There is currently no post-vaccination time limit on fully vaccinated status.

This guidance applies to COVID-19 vaccines currently either approved or authorized for emergency use by the U.S. Food and Drug Administration (Pfizer-BioNTech, Moderna, and Johnson & Johnson [J&J;]/Janssen COVID-19 vaccines). This guidance can also be applied to COVID-19 vaccines that have been listed for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford). More information is available at Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC.

Q: Should agencies inquire regarding the vaccination status of federal employees and onsite contractors?

A: Given the different safety protocols for individuals who are fully vaccinated and those who are not fully vaccinated, agencies need to ask about the vaccination status of federal employees and onsite contractors. Employees and onsite contractors must attest to the truthfulness of the response they provide. If an employee or onsite contractor chooses not to provide a response, they will be treated as unvaccinated for the purpose of agency safety protocols. In requesting this information, agencies should comply with any applicable federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act, and any applicable collective bargaining obligations. When an employee or contractor discloses that they are unvaccinated or declines to complete the attestation, agencies should treat that individual as not fully vaccinated for purposes of implementing safety measures, including with respect to mask wearing, physical distancing, testing, travel, and quarantine.

Q: Should agencies inquire regarding the vaccination status of visitors to federal buildings?

A: Visitors to federal buildings should be asked to provide information about vaccination status. In requesting this information, agencies should comply with any applicable federal laws, including requirements under the Privacy Act and the Paperwork Reduction Act. Visitors who are not fully vaccinated or who decline to provide information about their vaccination status must provide proof of a negative COVID-19 test from no later than the previous 3 days prior to entry to a federal building.

These requirements related to the provision of information about vaccination and provision of proof of a recent negative COVID-19 test do not apply to members of the public entering a federal building or federal land to obtain a public service or benefit. If they are not fully vaccinated, these visitors must comply with all relevant CDC guidance, including wearing a mask and physically distancing from other people.

Q: Are agencies required to establish different safety protocols for fully vaccinated and not fully vaccinated individuals?

A: Yes. Fully vaccinated individuals do not need to physically distance, undergo screening testing, or have restrictions on their official travel (although they still must comply with any local requirements and relevant CDC guidance for fully vaccinated individuals while traveling). Fully vaccinated individuals in areas of substantial or high transmission (see the CDC COVID-19 Data Tracker County View) need to wear a mask in public indoor settings. Fully vaccinated individuals in areas of low or moderate transmission do not need to wear a mask.

Fully vaccinated individuals might choose to wear a mask regardless of the level of transmission for a variety of reasons.

Individuals who are not fully vaccinated or who decline to provide information about their vaccination status must wear masks regardless of community transmission level, physically distance, and undergo screening testing weekly or twice-weekly, and their official travel is restricted.

In order to be treated as fully vaccinated pursuant to agency COVID-19 workplace safety plans and protocols, employees and onsite contractors must attest that they are fully vaccinated by signing a form provided by the agency. Visitors also will be asked to provide information about their vaccination status. Individuals who decline to provide information on their vaccination status will be treated as not fully vaccinated for purposes of agency COVID-19 workplace safety

plans and protocols. Visitors who are not fully vaccinated must provide proof of a negative COVID-19 test that occurred within the previous 3 days prior to entry to a federal building.

Individuals entering a federal building or federal land to obtain a public service or benefit do not need to provide information about their vaccination status or provide proof of a negative COVID-19 test. If they are not fully vaccinated, they must comply with all relevant CDC guidance, including wearing a mask.

Q: What safety protocols should an agency apply to employees and onsite contractors prior to establishing a means of determining vaccination status consistent with this guidance?

A: Agencies may take a reasonable period of time to establish a program for determining the vaccination status of employees and onsite contractors consistent with this guidance. Prior to an agency establishing such a program, they should continue to utilize their current means of determining the safety protocols that apply to specific employees and contractors.

NEW **Q: How should an agency ask employees about their vaccination status?**

A: Agencies should ask employees to complete the Certification of Vaccination form ("form" or "disclosure form"). By completing the form, employees will provide information about their vaccination status and attest to the truthfulness of that information. Individuals who do not complete the form will be treated as not fully vaccinated for purposes of agency safety protocols.

The Safer Federal Workforce Task Force has produced a template email that agencies should use as a means for contacting employees and distributing the Certification of Vaccination form. For purposes of this email, an "employee" means an employee of the agency, including a current civilian federal employee or a member of the uniformed services (including a reservist or member of the National Guard on active duty). For those employees who do not have access to email, agencies should determine the best method of distribution.

Agencies are able to maintain these employee disclosures, under the authorities of the Office of Personnel Management's regulations for employee medical files (5 C.F.R. part 293 subpart E) and OPM/GOVT-10, Employee Medical File System of Records, 75 Fed. Reg. 35099 (June 21, 2010), amended 80 Fed. Reg. 74815 (Nov. 30, 2015). Agencies that are not subject to OPM's regulations (or who employ categories of employees not covered by OPM/GOVT-10) must give their employees an alternative Privacy Act statement.

Please note that contractors and visitors will also be asked, under most circumstances, to fill out the Certification of Vaccination form – however, agencies **should not be** collecting and

maintaining contractor and visitor disclosures at this time unless an agency has a system of records notice that covers its collection of this information. Please see below for more information concerning visitors and contractors.

NEW **Q: How should an agency ask onsite contractors about their vaccination status?**

A: Agencies should provide onsite contractors with the Certification of Vaccination form when they enter a federal building or federally controlled indoor worksite.

Unless an agency has an existing system of records notice that permits it to collect and maintain this information on its contractors, agencies will direct onsite contractors to complete the Certification of Vaccination form and keep it with them during their time on federal premises—they may be asked to show the form upon entry to a federal building or federally controlled indoor worksite and to a federal employee who oversees their work. Onsite contractors who are not fully vaccinated (or who decline to disclose vaccination status) will either be enrolled in the agency's testing program or required to show proof of a negative COVID-19 test result from within the previous 3 days before entry to a federal building or federally controlled indoor worksite.

Agencies may email the form to contractors in advance of their time on-site or utilize a unique tool or application to share the form with contractors and enable them to easily complete it, but the agency will not maintain Certification of Vaccination forms from contractors at this time unless an agency has a system of records notice that covers its collection of this information from onsite contractors. Any such collection, storage, or maintenance of the attestation disclosure forms may implicate the Privacy Act and Paperwork Reduction Act.

If authorized and consistent with the terms of the contract, an agency may work with a contracting company to facilitate compliance by its onsite employees with the agency's safety protocols, such as by having the company certify that all onsite contractors are fully vaccinated.

NEW **Q: How should an agency ask visitors about their vaccination status?**

A: Agencies should provide visitors with the Certification of Vaccination form when they enter a federal building or federally controlled indoor worksite. Unless an agency has an existing system of records notice that permits it to collect and maintain this information on visitors, agencies will direct visitors to complete the Certification of Vaccination form and keep it with them during their time on federal premises—visitors may be asked to show the form upon entry to a federal building or federally controlled indoor worksite. If they are not fully

vaccinated or decline to answer, they will be required to show a negative COVID-19 test result from within the previous three days.

Agencies may email the Certification of Vaccination form to visitors in advance of arrival or utilize a tool or application to share the form with visitors and enable visitors to easily complete it, but the agency will not maintain Certification of Vaccination forms from visitors unless an agency has a system of records notice that covers its collection of this information from visitors. Any such collection, storage, or maintenance of the attestation disclosure forms may implicate the Privacy Act and Paperwork Reduction Act.

Individuals entering a federal building, federally controlled indoor worksite, or federal land to obtain a public service or benefit do not need to complete the form or show documentation of a negative COVID-19 test result. However, if they are not fully vaccinated, they must comply with all relevant CDC guidance and safety protocols, including mask-wearing and physical distancing requirements.

NEW **Q: Should agencies request documentation to verify an employee's vaccination status?**

A: Agencies should not request documentation to verify an employee's vaccination status. If the agency receives a good faith allegation that strongly suggests that an employee made a false statement on the Certification of Vaccination form, the agency may request documentation as part of its investigation into the alleged false statement. If an employee who has attested to being vaccinated exhibits symptoms of COVID-19 illness, the agency should apply its safety protocols, but this is not an appropriate reason to request documentation to verify an employee's vaccination status.

NEW **Q: What if an employee is not vaccinated due to a medical or religious reason?**

A: Employees who are not vaccinated due to medical or religious reasons should check either "I have not been vaccinated" or "I decline to respond" on the Certification of Vaccination form and must follow the safety protocols in place for not fully vaccinated persons. After submitting the form, they may then use the agency's established reasonable accommodations process to seek an accommodation, if necessary, related to agency safety protocols or procedures.

NEW **Q: Are there penalties for providing false information on the vaccination attestation form?**

A: Federal employees who make a false statement on the Certification of Vaccination form could be subject to an adverse personnel action, up to and including removal from their position. It is also a federal crime (18 U.S.C. § 1001) for anyone to provide false information on

the form. Falsification could also affect continuing eligibility for access to classified information or for employment in a national security position under applicable adjudicative guidelines.

Declining to answer—including selecting "I decline to respond" on the Certification of Vaccination form—does not constitute providing false information.

NEW **Q: If an agency already has information on an employee's vaccination status, do they need to utilize the form?**

A: In some cases, agencies may have information on the vaccination status of certain employees—for example, if the agency administered the vaccine to that employee. Where the agency already has the requisite information regarding vaccination status, it can utilize that information for purposes of determining the proper safety protocols to apply to that individual, consistent with the requirements of the Privacy Act. An agency is not required to collect duplicative information through the Certification of Vaccination form, if not necessary. However, if an agency has not collected this information from employees, it should use the Certification of Vaccination form to do so.

NEW **Q: Which individuals within an agency should have access to information on employees' vaccination status?**

A: The Privacy Act permits disclosure within the agency to employees "who have a need for the record in the performance of their duties." 5 U.S.C. 552a(b)(1). Agencies should only disseminate information to the appropriate agency officials who have a need to know to ensure effective implementation of the safety protocols, which, in many cases, will include the supervisor level. Agencies must comply with the requirements of the Privacy Act at all times. Agencies should consult with their Senior Agency Official for Privacy on any questions related to Privacy Act requirements.

NEW **Q: How should an agency maintain this employee information once it is received?**

A: Agencies have unique operational environments and may develop their own processes to maintain submissions of Certification of Vaccination forms in compliance with all applicable laws and in accordance with their agency's records management policies. Agencies may also develop and utilize tools and applications to maintain submissions of disclosure forms.

The Certification of Vaccination form's Privacy Act statement refers to the Government-wide system of records (OPM/GOVT-10) for employee medical files (EMFs), which is governed by OPM regulations (5 C.F.R. part 293, subpart E). Under those rules, each agency must have written instructions for its EMF system with appropriate safeguards. Agencies that are not subject to OPM's regulations (or who employ categories of employees not covered by OPM/GOVT-10)

must give their employees an alternative Privacy Act statement. As a general rule, this information should not be maintained in the Official Personnel Folder.

Agencies are encouraged to take steps to promote privacy and IT security, while also providing the relevant information to those who need to know in order to implement the safety protocols. Agencies should consult with their Agency Records Officer, Chief Information Officer, and Senior Agency Official for Privacy to determine the best means to maintain this information to meet the agency's needs.

NEW **Q: Should agencies provide a means for individuals to update their vaccination status?**

A: Yes. Employees should submit a new Certification of Vaccination form when their vaccination status changes.

NEW **Q: Should supervisors collect information on vaccination status directly from employees?**

A: Agencies should ask employees to complete the Certification of Vaccination form and should designate the appropriate agency official to whom the completed form should be submitted.

NEW **Q: What type of negative COVID-19 test result must a visitor or onsite contractor who is not fully vaccinated show documentation of in order to enter a federal building?**

A: Agencies may determine what types of tests a visitor or onsite contractor can show documentation of in order to enter a federal building, provided that the tests are authorized by the U.S. Food and Drug Administration and produce a dated result. Note that an onsite contractor enrolled in an agency testing program does not need to show a recent negative COVID-19 test result.

NEW **Q: Do agencies need to ask employees on maximum telework or remote workers about their vaccination status?**

A: Yes, agencies should provide the Certification of Vaccination form to all employees, including employees on maximum telework and remote workers.

NEW **Q: If an agency has a system of records notice that covers its collection of information on vaccination status from onsite contractors or visitors, can the agency collect that information?**

A: Yes, if an agency has a system of records notice that covers its collection of the requisite information—as reflected in the Certification of Vaccination form—from onsite contractors or

visitors consistent with the Privacy Act, it may do so. The agency should ensure such a collection is also consistent with the Paperwork Reduction Act.

NEW **Q: If a federal employee seeks to enter space under the control of another agency, must they complete a Certification of Vaccination form at that agency?**

A: Yes, federal employees are treated as visitors during their visit to another agency, meaning they would need to complete a Certification of Vaccination form and, if they are not fully vaccinated or decline to disclose their status, they would need to show proof of a negative COVID-19 test result within the past 3 days. As with other visitors, the employee should keep the form with them during their time onsite at the other agency.



For questions or comments, email the Safer Federal Workforce Task Force at SaferFederalWorkforce@gsa.gov

The Wayback Machine - https://web.archive.org/web/20210725055835/https://www.whiteh...

BRIEFING ROOM

Press Briefing by Press Secretary Jen Psaki, July 23, 2021

JULY 23, 2021 • PRESS BRIEFINGS

James S. Brady Press Briefing Room

1:14 P.M. EDT

MS. PSAKI: Hi everyone. Happy Friday. Okay, a couple of notes for you at the top.

Today, the Biden-Harris administration took additional steps to provide stability and relief to homeowners who are still feeling the economic effects of the COVID-19 pandemic.

HUD, USDA, and the VA announced details to help people with government-backed mortgages stay in their homes through monthly payment reductions and potential loan modifications.

Homeowners could see reductions in their monthly payments of roughly 20 to 25 percent, allowing them to remain in their homes and build long-term equity.

We're working hard to get the word out to Americans who may benefit from these new programs. And thanks to the work of the Consumer Financial Protection Bureau and today's actions, most servicers of mortgages are required to provide borrowers information about these options.

Homeowners can visit ConsumerFinance.gov/Housing for up-to-date information and more details.

virus. You can also make your grandparents sick and your parents sick. That is factual information.

We're not — but we're not here to place blame or threats; we're here to provide accurate information.

Q She says that she doesn't know what else she can do at this point, that she's hit a brick wall with trying to convince people to get vaccinated. Is that a sign that perhaps the federal government should step in and issue mandates? And if not, are you putting the needs of unvaccinated people ahead of the needs of vaccinated people?

MS. PSAKI: Well, I think the question here — one, that's not the role of the federal government; that is the role that institutions, private-sector entities, and others may take. That certainly is appropriate. Also, local communities are going to take steps they need to take in order to protect people in their communities.

I will say: We understand her frustration, and we understand the frustration of leaders out there and public voices who are trying to say the right thing, advocate for the efficacy of the virus, save people in their communities.

What our role is and what we are going to continue to do is make the vaccine available. We're going to continue to work in partnership to fight misinformation. And we're going to continue to advocate and work in partnership with local officials and — and trusted voices to get the word out.

Q And is there something to be learned from our neighbors to the north — Canada? They got a much slower start. They didn't have nearly as many vaccines as we did early on. And yet, now they've shot past us, and 70 percent of their population is at least partially vaccinated. What's the difference between the two countries? What can we learn from their experience?

MS. PSAKI: Well, first, I would say 162 million Americans are now vaccinated. That certainly is a positive step. We're the first to say and we have long said that that's not enough. We need to ensure more people and more communities are vaccinated. And it is now — we reached a point where

Consolidated Department of Defense Coronavirus Disease 2019 Force Health Protection Guidance

This guidance issued by the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) presents a uniform and consolidated DoD policy for the Department's response to the coronavirus disease 2019 (COVID-19) pandemic and serves as the DoD COVID-19 Workplace Safety Plan.[1] Implementation of this guidance will comply with: 1) applicable court orders, Presidential directives, and Office of Management and Budget (OMB) and Safer Federal Workforce Task Force guidance; and 2) applicable labor obligations to the extent such obligations do not hinder the DoD Components' ability to carry out their missions during this public health emergency. Prior delegations and exceptions made pursuant to the rescinded references remain valid unless rescinded by the authorizing official. Individual sections of this guidance will be updated as necessary by the USD(P&R).

This guidance will be posted, and updated as necessary, at: https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/. DoD Components should monitor this website to obtain the most current version of this guidance. Changes from the previous version will be identified in bold and italics.

Furthermore, this guidance consolidates, incorporates, and rescinds the following policy and guidance:

- Secretary of Defense Memorandum, "Guidance for Commanders' Risk-Based Responses and Implementation of the Health Protection Condition Framework During the Coronavirus Disease 2019 Pandemic," April 29, 2021
- Secretary of Defense Memorandum, "Use of Masks and Other Public Health Measures," February 4, 2021
- Secretary of Defense Memorandum, "Updated Conditions-based Approach to Coronavirus Disease 2019 Personnel Movement and Travel Restrictions." March 15, 2021
- Secretary of Defense Memorandum, "Way Forward for SARS-CoV-2 Testing Within the Department of Defense," April 29, 2021
- Deputy Secretary of Defense Memorandum, "Updated Coronavirus Disease 2019 Guidance Related to Travel and Meetings," September 24, 2021
- Deputy Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of DoD Civilian Employees," October 1, 2021
- Under Secretary of Defense Memorandum, "Administrative Leave for Coronavirus Disease 2019 Vaccination of Department of Defense Employees," April 14, 2021
- Under Secretary of Defense Memorandum, "Force Health Protection Guidance for the Novel Coronavirus," January 30, 2020, and all supplements.
- Under Secretary of Defense Memorandum, "Civilian Personnel Guidance for DoD Components in Responding to Coronavirus Disease 2019," March 8, 2020

[1] Executive Order (EO) 13991, "Protecting the Federal Workforce and Requiring Mask-Wearing," January 20, 2021.

EXECUTIVE SUMMARY

The DoD is committed to providing safe working environments across the entire DoD enterprise, which consists of an approximately 2.9 million-person global workforce deployed or stationed in nearly 150 countries, including military Service members and their families, and DoD civilian and contractor personnel that work in a highly complex and large number of diverse and unique environments. This force health protection (FHP) Guidance ("Guidance") was developed to protect the DoD workforce, contractor personnel, other occupants, and visitors (collectively referred to as "personnel") before, during, and after our orderly and final return to the physical workplace ("final reentry"). The Guidance is intended to meet the direction of the President's EOs[2] and guidance from the Safer Federal Workforce Task Force ("Task Force") and OMB,[3, 4] and articulate steps the DoD has been and will be taking to halt the spread of COVID-19.

Consistent with Task Force and OMB guidance, this Guidance includes policies and procedures that incorporate the best available data and science-based measures and activities that focus on health and safety and on workplace operations. DoD uses the latest guidance from the Centers for Disease Control and Prevention (CDC), and requirements from the Occupational Safety and Health Administration (OSHA) and other relevant Federal agencies as the starting point for developing COVID-19 policy and guidance.

The Department began publishing FHP guidance and policy to address COVID-19 in January 2020. In February 2021, the Secretary of Defense directed the review of all guidance and policy memoranda previously issued for COVID-19.[5] The review was completed in April 2021, and subsequent updates align DoD COVID-19 policy and guidance with current Task Force, OMB, CDC, and OSHA guidance as appropriate.

The DoD COVID-19 Task Force is responsible for recommending updated DoD COVID-19 policy. The Deputy Secretary of Defense and the Vice Chairman of the Joint Chiefs of Staff co-chair the DoD COVID-19 Task Force which assembles as needed for meetings virtually and in person and includes representatives from senior leadership across the Department, including the Secretaries of the Military Departments (MILDEPs), Under Secretaries of Defense, and Combatant Commanders.

DoD has long recognized the threat posed by pandemics and disease outbreaks and has previously issued guidance, planning, and policy documents to prepare for and respond to such

[2] EO 14042, "Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors," September 9, 2021; EO 14043, "Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees," September 9, 2021.
[3] Documents from the Safer Federal Workforce Task Force are available at: https://www.saferfederalworkforce.gov/overview/.
[4] Office of Management and Budget Memorandum, Office of Personnel Management, and General Services Administration, M-21-25, "Integrating Planning for A Safe Increased Return of Federal Employees and Contractors to Physical Workplaces with Post-Reentry Personnel Policies and Work Environment," June 10, 2021
[5] Secretary of Defense Memorandum, "Strategic Review and Reissuance of All Coronavirus Disease 2019 Policy Documents," February 2, 2021.

threats. The DoD also recognizes that successfully managing the COVID-19 pandemic requires the flexibility to adapt to changing conditions (e.g., variants, and disease prevalence or virulence) and new information (e.g., evolving best health and safety practices).

The DoD is committed to protecting its workforce and stakeholders from the effects of the COVID-19 pandemic, while preserving our ability to complete its mission. As data becomes available, science-based evidence emerges, and the CDC, OSHA, and other cognizant agencies, departments, and other elements of the Federal Government revise and develop new recommendations to protect the workforce, the DoD will incorporate them into its current and future policies and guidance as appropriate.

SECTION 8: PROTECTION OF PERSONALLY IDENTIFIABLE INFORMATION RELATED TO COVID-19

8.1. GENERAL.

Under this Force Health Protection Guidance, the DoD may collect and maintain sensitive and private information about individuals, including medical information. All personally identifiable information (PII) on individuals must be appropriately safeguarded. In implementing this guidance, DoD Components may collect, use, maintain, and/or disseminate only the minimum amount of PII necessary to prevent the spread of COVID-19 and to protect personnel in DoD workplaces. All personally identifiable information (PII) on individuals must be appropriately safeguarded under the Privacy Act of 1974 and DoDI 5400.11, "DoD Privacy and Civil Liberties Programs."

Due to the public health emergency, DoD Components are authorized to collect COVID-19 information from individuals whose place of duty is in the DoD workplace, to the extent such collection is necessary to implement the guidance above on workplace access and restriction. DoD Components are authorized to use DD Form 3112, "Personnel Accountability and Assessment Notification for Coronavirus Disease 2019 (COVID-19) Exposure," to collect this information (e.g., affected individual information, type of confirmed or possible health or safety issue). This form is located at: https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd3112.pdf.

Currently, the requirement for all Federal civilian employees to be vaccinated is not in effect. A U.S. district court judge issued a nationwide preliminary injunction prohibiting implementation and enforcement of civilian employee vaccination requirements based on EO 14043. Requirements subject to the injunction and not currently in effect are included in this guidance in a strikeout form for ease of reinstitution by USD(P&R) should the injunction be lifted.

8.2. ADDITIONAL REQUIREMENTS FOR INFORMATION COLLECTED FROM DOD CIVILIAN EMPLOYEES.

Medical information obtained from DoD civilian employees, including vaccination status, will be accessible only to immediate supervisors, authorized human resources officials, ~~and, for exemption requests, Decision Authorities and subject matter experts,~~ who must access the information to implement the guidance in this memorandum. The Rehabilitation Act's requirements on confidentiality of medical information apply whether or not a DoD civilian employee has a disability.

DoD personnel will use appropriate safeguards in handling and storing DoD civilian employee medical information, including a DoD civilian employee's proof of vaccination; any medical information on the DD Forms 3175, 3176, and 3177, and COVID-19 test results. Appropriate safeguards may include encrypting emails and electronic files, and role-based access

United States Government Accountability Office

Report to Congressional Addressees

June 2021

COVID-19

DOD Has Focused on Strategy and Oversight to Protect Military Servicemember Health

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vaccinated or recovered from a laboratory-confirmed diagnosis of COVID-19 infection.[42]

Command-level restriction of movement protocols are sometimes more restrictive than DOD guidance or host nation requirements. For example, according to U.S. European Command officials, even though Germany waives its quarantine requirement for military travel, the commander requires that servicemembers quarantine for 14 days upon arrival in Germany in an abundance of caution. Naval Hospital Okinawa officials told us that they require incoming personnel from outside the island to conduct a 14-day restriction of movement upon arrival even if they had completed a 14-day restriction of movement immediately before traveling to Okinawa. This protocol, according to MTF officials, reduces the risk of infections from personnel traveling through high-risk locations (i.e., those with a high incidence of COVID-19) and provides assurance to the Okinawan Prefectural Government.

Host nation requirements can also be more restrictive about entry requirements than DOD generally requires with its restriction of movement procedures. For example, according to U.S. Indo-Pacific Command officials, the Republic of Palau agreed to let U.S. Marine Forces Pacific enter for training exercises if they followed strict procedures—specifically, all servicemembers were tested, sent out to sea for 21 days, tested again, quarantined for 14 more days, and then tested again before gaining entry.

Establish COVID-19 testing protocols. Detection of COVID-19 through testing is a key element of DOD's force health protection strategy. Yet, senior DOD officials explained to us that testing is but one component of a broader strategy in which the prevention and risk mitigation measures discussed previously are paramount. This is because a negative test can only be interpreted as a failure to detect the virus at a single point in time.

[42]Under Secretary of Defense for Personnel and Readiness Memorandum, *Force Health Protection Guidance (Supplement 20) – Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic* (Apr. 12, 2021). In addition, in May 2021, DOD updated guidance for personnel deploying or redeploying to permit certain limited exemptions to restriction of movement periods, or reduced periods of restriction of movement. Under Secretary of Defense for Personnel and Readiness Memorandum, *Force Health Protection Guidance (Supplement 16) Revision 1 – Department of Defense Guidance for Deployment and Redeployment of Individuals and Units During the Coronavirus Disease 2019 Pandemic* (May 4, 2021).

That is, a negative test could be accurate or false and does not predict future infection.

DOD is using three types of COVID-19 tests—diagnostic, screening, and surveillance—to separate infected individuals from healthy populations, determine the disease incidence, and break the chain of transmission. Separately, certain DOD laboratories are also performing serology tests to identify the number of servicemembers with COVID-19 antibodies, and sequencing tests—a specific type of surveillance test—to identify variations of the virus circulating among servicemembers.

DOD's diagnostic, screening, and surveillance testing protocols generally align with CDC guidance. For example, DOD requires that confirmation of a COVID-19 diagnosis should be performed with a molecular test.[43] We also found that DOD's testing strategy is consistent with FDA guidance for diagnostic and screening testing.[44] For example, DOD's force health protection guidance directs DOD components to use FDA-certified laboratories and COVID-19 tests with an emergency use authorization (EUA) from the FDA.

DOD prioritizes diagnostic testing for all individuals with COVID-19 symptoms or exposure, consistent with CDC guidance. Doing so allows health care providers to document a COVID-19 infection in servicemembers' medical records and continue or begin isolation and other mitigation steps.

Further, the nature of SARS-CoV-2 in terms of its transmission rate among asymptomatic individuals prompted DOD to include screening and surveillance testing as part of its strategy, according to DOD officials.[45] As a result, the department has executed testing on a scale never needed nor envisioned for a disease prior to COVID-19. However, persistent global supply shortages have led DOD to adopt a resource-informed testing approach. In accordance with the tiered framework described

[43]Molecular tests are typically performed in a laboratory to detect the virus's genetic material. Polymerase-chain reaction technology is an example of a molecular test. The CDC defines a confirmed case as meeting confirmatory laboratory evidence for COVID-19 (i.e., a positive molecular test).

[44]FDA, *COVID-19 Test Uses: FAQs on Testing for SARS-CoV-2* (Feb. 18, 2021).

[45]Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is the virus that causes the disease COVID-19.

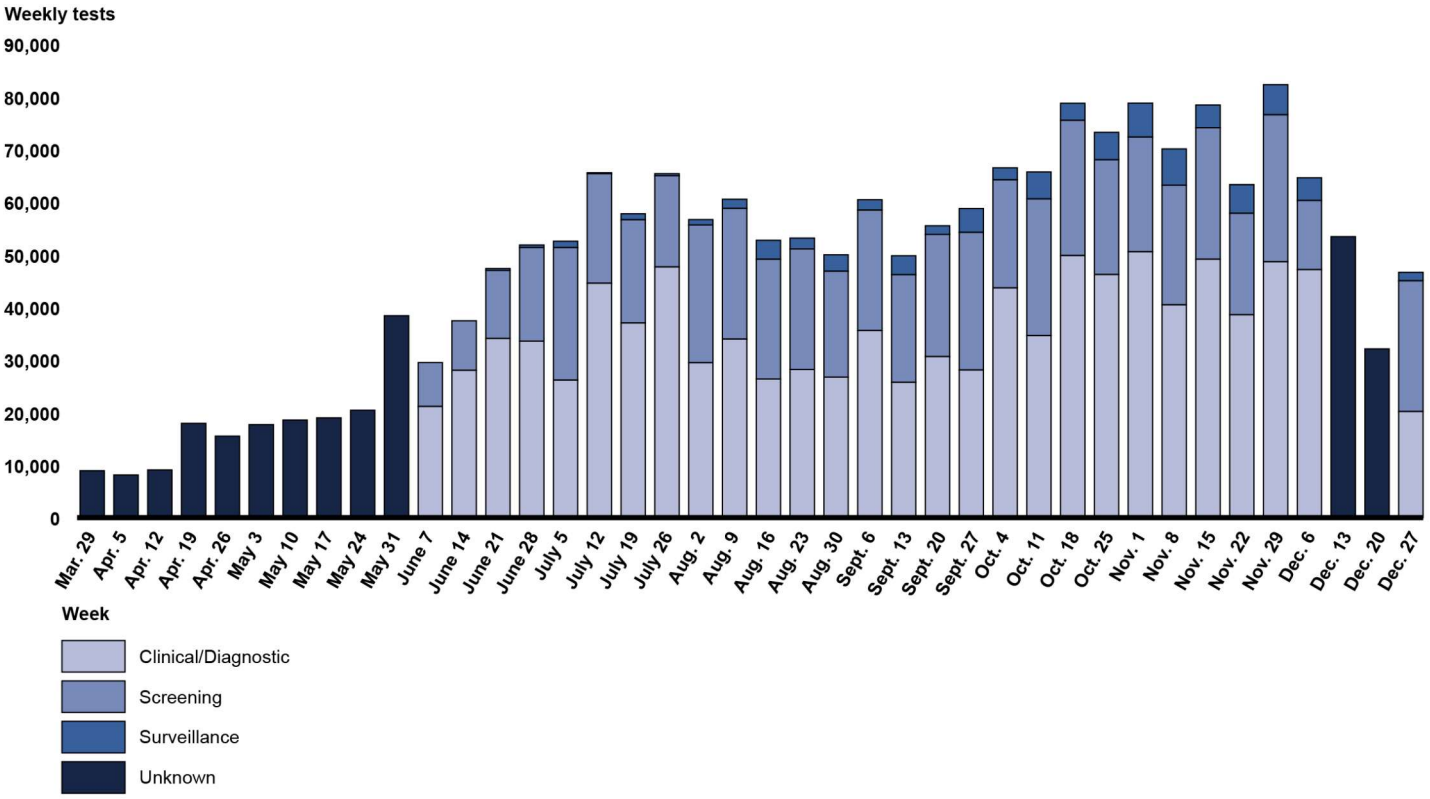
previously in table 2, screening tests are performed for certain servicemembers before deployment or training, in order of priority. Randomized surveillance tests are last in order of priority, as the availability of testing resources allow.[46]

Figure 5 shows that DOD has generally increased its overall weekly tests from about 10,000 during the last week of March 2020, to 65,000 tests per week by the last week of July 2020. After decreasing numbers of tests through the end of August 2020, DOD generally increased its overall weekly tests again from about 50,000 in late September, to about 80,000 during the last week of November 2020. Where data on test type were available, clinical/diagnostic tests made up the largest shares of the tests, followed by screening tests. Surveillance tests made up the smallest shares of the tests.

[46]Under Secretary of Defense for Personnel and Readiness Memorandum, *Force Health Protection Guidance (Supplement 11)- Department of Defense Guidance for Coronavirus Disease 2019 Surveillance and Screening with Testing* (June 11, 2020).

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Figure 5. Department of Defense Weekly COVID-19 Tests in 2020, by Type, for Active-Duty Servicemembers



Source: GAO review of data from the Department of Defense's COVID-19 Task Force. | GAO-21-321

Notes: Data in the figure represent the total number of tests conducted in a given week, including those for servicemembers who were tested more than once. Thus, the total numbers of servicemembers tested each week are generally lower than the numbers in this figure. The data include members of the active components of the military services, and Reserve and National Guard members serving on active duty at the time of the test. Clinical/diagnostic tests are clinically indicated for patient care; screening tests are performed prior to group movements or engagement in activities; and surveillance tests are performed to identify incidence of COVID-19 in a specified population or geographic location. All tests prior to standardized reporting are labeled "Unknown." According to a DOD COVID-19 Task Force official, the Task Force did not report data on test by type for those conducted over the winter holidays the weeks of December 13 and December 20, 2020. Lower testing numbers in December may be due to fewer individuals seeking testing during the holidays.

According to DOD officials, tests for servicemembers in tiers 1 and 2 have comprised the majority of screening tests each week because limitations in supplies have constrained available tests for tiers 3 and 4. The officials attributed this to a lack of predictability in the monthly supply chain, persistently high global demand, and market competition. We have previously reported on similar challenges with COVID-19 testing as part of the whole-of-government response. In September 2020, we found that the FDA and the Federal Emergency Management Agency identified

shortages, and officials from seven of eight states we interviewed in July and August 2020 identified previous or ongoing shortages of testing supplies—challenges that we found to be attributed to a supply chain with limited domestic production and high global demand.[47]

DOD officials stated that, even if resources were unconstrained, testing every servicemember every week would not be helpful or feasible for improving outcomes. Notwithstanding persistent challenges, officials stated that they are exploring ways to increase weekly screening tests for servicemembers in tiers 3 and 4, and surveillance tests. Yet, a precise number of ideal weekly tests is difficult to determine due to tradeoffs between the speed, accuracy, and cost of tests by type, as well as lack of consensus in the scientific community about the best testing protocol. Similarly, in January 2021 we found that the Department of Health and Human Services—a lead federal agency for the COVID-19 response—has not issued a comprehensive and publicly available national testing strategy.[48] We recommended that the department develop and publish a strategy, which we believe could be done efficiently and flexibly. As of March 2021 it had not yet done so.

To increase weekly testing across its approximately 2.1 million active-duty and reserve forces, DOD has taken two key actions. First, DOD expanded and diversified its testing capabilities. Due to supply constraints associated with COVID-19 tests, the department added new testing technologies to its toolkit. As a result, DOD testing platforms now include laboratory-based molecular tests, point-of-care molecular tests, point-of-care antigen tests, as well as contracts with commercial laboratories. Second, DOD increased testing capacity by expanding the number of laboratories. In July 2020, DOD had 125 department laboratories certified for COVID-19 testing around the globe with the capacity to conduct over 200,000 tests per week. By November 2020, the number of operational DOD laboratories had increased to 158 with the overall capacity to conduct nearly 300,000 tests per week. As a result, the median time between tests (specimen collection) and delivery of results for DOD in-house laboratory tests has been less than 24 hours since late August 2020.

Establish protocols to prioritize and distribute antivirals and vaccines. DOD recommends a limited number of supplemental

[47]GAO-20-701.

[48]GAO-21-265.

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therapeutics to treat COVID-19 infection in accordance with National Institutes of Health guidelines, including remdesivir for hospitalized patients with severe disease and dexamethasone for patients who require supplemental oxygen.[49] DOD is currently researching additional therapeutics including monoclonal antibodies, polyclonal antibodies, plasma-related products, antivirals, and other small molecules. We discuss DOD's research and development programs later in this report.

DOD developed an implementation plan to provide COVID-19 vaccines to eligible personnel, including servicemembers and their dependents, DOD civilian employees, military retirees, and DOD contractor personnel. Due to initial limited supply, the vaccine implementation plan established a prioritization scheme mirroring CDC guidance that focuses first on personnel providing direct medical care, critical and essential support personnel, deploying forces, and those at highest risk for developing severe illness from COVID-19.[50]

According to DOD officials, the COVID-19 vaccine implementation plan is based on the department's influenza vaccine plan. However, officials noted that this vaccination project is unprecedented in recent history and involves several unique logistical challenges. For example, unlike influenza vaccines, the first two COVID-19 vaccines that the FDA authorized for emergency use (manufactured by Pfizer-BioNTech and Moderna) require two doses per person and a temperature-controlled supply chain. In addition, there are typically one or two influenza vaccines that DOD distributes in a given year; whereas five or more COVID-19 vaccines could be authorized or approved by the FDA for use in the same year (including the two vaccines authorized for emergency use in December 2020, and a third vaccine, manufactured by Johnson & Johnson, authorized for emergency use in February 2021). Despite these complexities, DOD officials stated that they believe the experience and knowledge gained from annual influenza vaccine distribution will help the department distribute the COVID-19 vaccines.

[49]Remdesivir is an antiviral medication approved October 22, 2020 by the FDA for treatment of certain COVID-19 patients requiring hospitalization. Dexamethasone is a steroid with anti-inflammatory effects.

[50]We discuss DOD's vaccine plan, including its prioritization scheme, in more detail in GAO-21-387. Our next government-wide report on the federal response to COVID-19 will be issued in July 2021 and will include information about DOD's vaccination efforts.

DOD initially made COVID-19 vaccination voluntary due to federal law that says a vaccine released under an EUA cannot be made mandatory.[51] However, the President has authority to waive this provision and require members of the armed forces to take a vaccine released under an EUA in the interests of national security.[52] According to DOD officials, DOD will revisit its decision to make vaccination voluntary if the FDA gives a vaccine full approval.

DOD began limited distribution of the Pfizer-BioNTech vaccine to the first of 16 locations on December 11, 2020 to gather lessons learned, make adjustments, and improve its process for subsequent distribution. According to DHA officials involved in overseeing the vaccine plan implementation, factors affecting the rate of vaccine administration have varied over time and by location. For example, the holidays in late December 2020 through mid-January 2021 and winter weather slowed vaccination efforts at U.S. sites. Officials stated that differences in the populations served by vaccination site (e.g., reserve or active component) has been another factor.

[51]21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

[52]10 U.S.C. § 1107a(a).

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0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Over-the-Counter Monograph Submissions in Electronic Format.'' This guidance provides information on providing electronic submissions to FDA under section 505G of the FD&C Act (21 U.S.C. 355h) (hereafter referred to as over-the-counter (OTC) monograph submissions). This guidance is intended to assist submitters by describing the electronic OTC monograph submissions requirement in section 505G(j) of the FD&C Act and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format.

Section 505G of the FD&C Act was added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Public Law 116–136, which was enacted on March 27, 2020. Section 505G(j) of the FD&C Act requires that all OTC monograph submissions must be in electronic format. As required by section 505G(l)(3) of the FD&C Act, this draft guidance, when finalized, specifies the format of electronic submissions under section 505G of the FD&C Act.

In support of the CARES Act, FDA agreed to specific performance goals and procedures described in the document entitled ''Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2018–2022,'' commonly referred to as the OMUFA commitment letter (the document can be accessed at *https://www.fda.gov/media/106407/download* and the document with updated goal dates for fiscal years 2021 to 2025 can be accessed at *https://www.fda.gov/media/146283/download*). In the OMUFA commitment letter, FDA committed to issuing this draft guidance under specific timelines.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Providing Over-the-Counter Monograph Submissions in Electronic Format.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under section 505G(o) of the FD&C Act, the Paperwork Reduction Act of 1995 does not apply to collections of information made under section 505G of the FD&C Act. This guidance is being issued to implement the provisions of section 505G(l)(3) of the FD&C Act, which specifies the format of electronic submissions to FDA under section 505G of the FD&C Act. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.*

Dated: September 23, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21007 Filed 9–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0987]

Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised); Immediately in Effect Guidance for Commercial Manufacturers and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance document related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE) entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised).'' FDA is issuing this guidance to provide FDA's revised enforcement policies and review priorities regarding certain novel coronavirus (COVID–19) tests for the duration of the public health emergency. Rapid detection of COVID–19 cases in the United States requires wide availability of testing to control the spread of this highly contagious infection. This document supersedes ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised)'' issued November 15, 2021. The guidance identified in this notice addresses issues related to the COVID–19 PHE and has been issued in accordance with the expedited process FDA announced in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. This guidance has been implemented without prior comment, but it remains subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidance is published in the **Federal Register** on September 28, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–0987 for ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))).

Submit written requests for a single hard copy of the guidance document entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised)'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3416, Silver Spring, MD 20993–0002, 301–796–6512.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance entitled ''Policy for Coronavirus Disease—2019 Tests During the Public Health Emergency (Revised),'' which supersedes the guidance of the same title issued November 15, 2021. FDA is issuing this guidance to provide FDA's updated enforcement policies and review priorities regarding certain novel coronavirus (COVID–19) tests for the duration of the public health emergency. Rapid detection of COVID–19 cases in the United States requires wide availability of testing to control the spread of this highly contagious infection.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb–3), the FDA Commissioner may authorize the use of unapproved medical products, or unapproved uses of approved medical products, in certain emergency circumstances, after the HHS Secretary has made a declaration of emergency or threat justifying authorization of emergency use, to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological, and nuclear threat agents when certain criteria are met (emergency use authorization (EUA)). As of August 15, 2022, FDA has authorized under EUA more than 439 tests for COVID–19, including more than 354 diagnostic and 85 serology or other immune response tests. Further, two molecular diagnostic COVID–19 tests have been granted marketing authorization through the traditional device premarket review pathways.

In the context of a public health emergency involving pandemic infectious disease, it is critically important that tests are validated because false results not only can negatively impact the individual patient but also can have a broad public health impact. False positive results for diagnostic tests, for example, can lead to unnecessary quarantine and potential further spread when presumed positive individuals are quarantined together, wasted contact tracing and testing resources, and delay in accurate diagnosis and appropriate treatment for the individual. False negative results can lead to lack of appropriate treatment for the individual and further spread of the disease.

FDA has continued to closely monitor the COVID–19 testing landscape and believes it is appropriate to update its policies to reflect the current needs of the pandemic. As explained throughout this updated guidance, FDA intends to review the EUA requests for a smaller subset of tests. Traditional marketing pathways remain available to all developers and FDA encourages developers of tests that fall outside the scope of the priorities outlined in this updated guidance to pursue those routes. In sum, FDA has revised this guidance to update the types of COVID–19 tests for which the Agency intends to review EUA requests, to discuss the use of the traditional premarket review pathways for other types of COVID–19 tests for which the Agency does not intend to review EUA requests, and to make minor updates to the enforcement policies.

On January 31, 2020, as a result of confirmed cases of COVID–19, and after consultation with public health officials as necessary, the Secretary of Health and Human Services (HHS), pursuant to the authority under section 319 of the Public Health Service Act (42 U.S.C. 247d), determined that a PHE exists and has existed since January 27, 2020, nationwide.[1] On March 13, 2020, there was a Presidential declaration that the COVID–19 outbreak in the United States constitutes a national emergency, beginning March 1, 2020.[2]

[1] Secretary of Health and Human Services, ''Determination that a Public Health Emergency Exists'' (originally issued on January 31, 2020, and subsequently renewed), available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx*.

[2] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (March 13, 2020), available at: *https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-*

In the **Federal Register** of March 25, 2020 (85 FR 16949) (the March 25, 2020, notice) (available at *https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf*), FDA announced various procedures for making available FDA guidances related to the COVID–19 PHE. The March 25, 2020, notice stated that due to the need to act quickly and efficiently to respond to the COVID–19 PHE and to allow FDA to rapidly disseminate Agency recommendations and policies related to COVID–19 to industry, FDA staff, and other stakeholders, prior public participation would not be feasible or appropriate before FDA implemented COVID–19-related guidances. FDA will continue to issue COVID–19-related guidances for immediate implementation without prior public comment (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and § 10.115(g)(2)). The guidances are available on FDA's web pages entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders'' (available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders*) and ''Search for FDA Guidance Documents'' (available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*.) Although this guidance has been implemented immediately without prior comment, FDA will consider all comments received and revise the guidance as appropriate (see § 10.115(g)(3)).

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The guidance represents the current thinking of FDA. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA). The collections of information in the following FDA regulations and guidances have been approved by OMB as listed in the table below. This guidance also contains a new collection of information not approved under a current collection. The new collection of information has been granted a public health emergency (PHE) waiver from the PRA by the Department of Health and Human Services (HHS) on March 19, 2020, under section 319(f) of the PHS Act. Information concerning the PHE PRA waiver can be found on the HHS website at *https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers*.

21 CFR part or guidance	Topic	OMB control No.	New collection covered by PHE PRA waiver
Emergency Use Authorization of Medical Products and Related Authorities; Guidance for Industry and Other Stakeholders.	Emergency Use Authorization	0910–0595	
''Administrative Procedures for CLIA Categorization; Guidance for Industry and Food and Drug Administration Staff'' and ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Guidance for Industry and Food and Drug Administration Staff''.	Administrative Procedures for Clinical Laboratory Improvement Amendments of 1988 Categorization.	0910–0607	
803	Medical devices; medical device reporting; manufacturer reporting, importer reporting, user facility reporting, distributor reporting.	0910–0437	
807, subpart E	Premarket notification	0910–0120	
814, subparts A through E	Premarket approval	0910–0231	
860, subpart D	De Novo classification process	0910–0844	
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions; pre-submissions	0910–0756	
			Voluntary templates to facilitate the preparation and submission of an Emergency Use Authorization request for various types of COVID–19 tests.

III. Electronic Access

Persons with access to the internet may obtain the guidance at:

- FDA web page entitled ''Guidance Documents (Medical Devices and Radiation-Emitting Products)'' available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*;
- FDA web page entitled ''COVID–19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders,'' available at *https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-*

disease-covid-19-outbreak/. On February 24, 2021, there was a Presidential Declaration continuing the national emergency concerning the COVID–19 pandemic beyond March 1, 2021. See Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic (February 24, 2021), available at *https://www.federalregister.gov/documents/2021/02/26/2021-04173/continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic*.

related-guidance-documents-industry-fda-staff-and-other-stakeholders;

- FDA web page entitled ''Search for FDA Guidance Documents'' available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*; or
- *https://www.regulations.gov*.

Dated: September 21, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–20828 Filed 9–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Biologics Evaluation and Research (CBER), Office of Tissues and Advanced Therapies (OTAT) has modified its organizational structures.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services on August 8, 2022, and effective on September 16, 2022.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD, 20705–4304, 301–796–3843.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganization of CBER, Office of Tissues and Advanced Therapies (OTAT).

CBER's mission is to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. With substantial growth in innovative, novel products, as well as a need to address an ever-changing landscape of potential public health threats, CBER is currently facing scientific, medical, and regulatory challenges that require changes to its structure.

Utilizing key tenets of CBER's modernization efforts, CBER will retitle OTAT to the Office of Therapeutic Products (OTP) and elevate OTP to a Super Office to manage its program at a macro level and to better position the Center to address an everchanging public health landscape. With the current and anticipated increase in workloads, the proposed structural changes will improve functional alignment, increase review capabilities, and enhance expertise on new cell and gene therapies. Additional supervisory positions will not only help to address this increased workload but will also provide advancement opportunities to facilitate recruitment and retention of highly qualified staff. The proposal creates flexibility and capacity for future growth in Full-Time Employees (FTEs) and workload, avoiding the need for continual reorganizations. The reorganization will position OTP to focus on commitments, including those negotiated with industry in the prescription drug user fee agreement (PDUFA) for FY 2023–2027, and other key priorities that protect public health. To advance the field and support the next generation of cell and gene therapies, OTP will continue to see growth in the Regenerative Medicine Advanced Therapy (RMAT) program, established in the 21st Century Cures Act.

The Food and Drug Administration's Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies, has been restructured as follows:

DCB. ORGANIZATION. The Center for Biologics Evaluation and Research is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Therapeutic Products (DCBG)
Administrative Staff (DCBG1)
Policy and Special Projects Staff (DCBG2)
Office of Gene Therapy CMC (DCBGF)
Division of Gene Therapy I (DCBGFA)
Gene Therapy Branch 1 (DCBGFA1)
Gene Therapy Branch 2 (DCBGFA2)
Gene Therapy Branch 3 (DCBGFA3)
Division of Gene Therapy II (DCBGFB)
Gene Transfer and Immunogenicity Branch (DCBGFB1)
Gene Therapy Branch 4 (DCBGFB2)
Gene Therapy Branch 5 (DCBGFB3)
Office of Cellular Therapy and Human Tissues CMC (DCBGG)
Division of Cell Therapy I (DCBGGA)
Cell Therapy Branch 1 (DCBGGA1)
Cell Therapy Branch 2 (DCBGGA2)
Cellular and Tissue Therapy Branch (DCBGGA3)
Division of Cell Therapy II (DCBGGB)
Tissue Engineering Branch 1 (DCBGGB1)
Tissue Engineering Branch 2 (DCBGGB2)
Tumor Vaccine and Biotechnology Branch (DCBGGB3)
Division of Human Tissues (DCBGGC)
Human Tissues and Reproduction Staff (DCBGGC1)
Office of Plasma Protein Therapeutics CMC (DCBGH)
Division of Hemostasis (DCBGHA)
Hemostasis Branch 1 (DCBGHA1)
Hemostasis Branch 2 (DCBGHA2)
Division of Plasma Derivatives (DCBGHB)
Plasma Derivatives Branch 1 (DCBGHB1)
Plasma Derivatives Branch 2 (DCBGHB2)
Office of Clinical Evaluation (DCBGI)
Division of Clinical Evaluation General Medicine (DCBGIA)
General Medicine Branch 1 (DCBGIA1)
General Medicine Branch 2 (DCBGIA2)
General Medicine Branch 3 (DCBGIA3)
General Medicine Branch 4 (DCBGIA4)
Division of Clinical Evaluation Oncology (DCBGIB)
Oncology Branch 1 (DCBGIB1)
Oncology Branch 2 (DCBGIB2)
Division of Clinical Evaluation Hematology (DCBGIC)
Benign Hematology Branch (DCBGIC1)
Malignant Hematology Branch (DCBGIC2)
Office of Pharmacology/Toxicology (DCBGJ)
Division of Pharmacology/Toxicology I (DCBGJA)
Pharmacology/Toxicology Branch 1 (DCBGJA1)
Pharmacology/Toxicology Branch 3 (DCBGJA2)
Division of Pharmacology/Toxicology II (DCBGJB)
Pharmacology/Toxicology Branch 2 (DCBGJB1)
Pharmacology/Toxicology Branch 4 (DCBGJB2)
Office of Review Management and Regulatory Review (DCBGK)
Division of Review Management and Regulatory Review I (DCBGKA)
Regulatory Review Branch 1 (DCBGKA1)
Review Management Support Branch 1 (DCBGKA2)
Division of Review Management and Regulatory Review II (DCBGKB)

May 2022

COVID-19

FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed

GAO Highlights

Highlights of GAO-22-104266, a report to congressional addressees

Why GAO Did This Study

Diagnostic testing for COVID-19 is critical to tracking the virus, informing treatment, and suppressing transmission. However, because COVID-19 is caused by a novel virus, no test existed at the beginning of the pandemic. Typically, medical devices, such as diagnostic tests, must be approved or cleared by FDA before they can be offered. However, FDA's EUA authority requires a lower level of evidence than the effectiveness standard normally required for FDA product approval; therefore, it can help tests become available in a shorter amount of time. Test developers submit EUA requests to FDA that include data on a test's performance, and FDA reviews the data to determine whether to grant an EUA.

GAO was asked to review FDA's oversight of tests for COVID-19. This report examines, among other things, 1) the actions FDA took to help make COVID-19 tests available for use, 2) the number of tests FDA authorized and those for which it exercised enforcement discretion, and 3) FDA's monitoring of these tests after they were available for use. GAO reviewed agency documentation, and interviewed FDA and associations that represent test developers.

What GAO Recommends

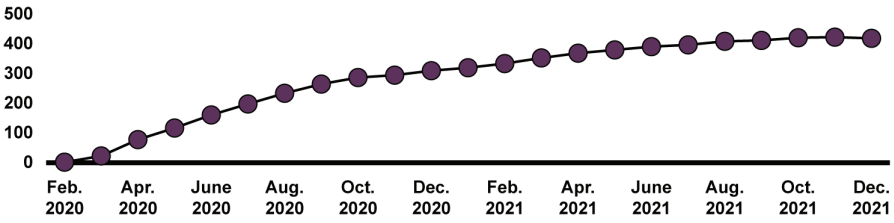
GAO recommends that FDA develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies. This policy should include the conditions under which FDA would begin and end the use of such discretion. The Department of Health and Human Services concurred with our recommendation.

View GAO-22-104266. For more information, contact Mary Denigan-Macauley at (202) 512-7144 or DeniganMacauleyM@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) took several actions aimed at increasing the availability of COVID-19 tests in the United States. This included granting emergency use authorizations (EUA) for more than 400 COVID-19 tests and sample collection devices by the end of 2021 (see figure). In a public health emergency, FDA may grant EUAs to temporarily allow the use of unapproved medical products, provided there is evidence that the product may be effective and that the known and potential benefits outweigh known and potential risks. FDA also exercised enforcement discretion for certain COVID-19 tests —that is, it did not object to laboratories' use of these COVID-19 tests before FDA had authorized them; this did not apply to tests that could be used at home. FDA's use of enforcement discretion helped increase test availability early in the pandemic.

Cumulative Number of COVID-19 Tests and Sample Collection Devices Authorized by FDA for Emergency Use, 2020-2021



Source: Food and Drug Administration (FDA). | GAO-22-104266

As of September 30, 2021, FDA had exercised its enforcement discretion for 370 tests. Test developers had submitted EUA requests for these tests, but FDA had not yet reviewed them. FDA officials told GAO they had concerns about the lack of review for these unauthorized tests, and as the number grew, the risks of this policy began to outweigh the benefits. Nevertheless, it was not until November 2021 that FDA updated its COVID-19 test policy with the intention of phasing out the agency's use of enforcement discretion and reducing the number of unauthorized tests. However, FDA has no policy for when it would begin and end exercising enforcement discretion for the use of unauthorized tests in a future public health emergency. Without such a policy, if FDA were to exercise similar enforcement discretion in the future, the agency could face the risk that tests with uncertain accuracy and reliability could be available for use for an extended period of time, even when a sufficient number of authorized tests are available. This could hamper an effective response and recovery during a crisis.

FDA monitors the performance of all COVID-19 tests—whether granted an EUA or not—through reports of performance problems submitted to FDA by test developers, health care providers, and consumers. According to FDA, this includes reports of false positive or false negative test results. By December 31, 2021, FDA had received more than 18,000 such reports for COVID-19 tests and took action to address identified problems. For example, FDA issued 10 letters to clinical laboratory staff and health care providers to inform them of safety concerns about COVID-19 tests.

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

PERSONNEL AND
READINESS

SEP - 7 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Force Health Protection Guidance (Supplement 23) – Department of Defense Guidance for Coronavirus Disease 2019 Vaccination Attestation and Screening Testing for Unvaccinated Personnel

References:
(a) Safer Federal Workforce Task Force, "COVID-19 Workplace Safety: Agency Model Safety Principles," July 29, 2021
(b) Secretary of Defense Memorandum, "Mandatory Coronavirus Disease 2019 Vaccination of Department of Defense Service Members," August 24, 2021
(c) DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Programs," Change 1, December 8, 2020
(d) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 15) Revision 2 – Department of Defense Guidance for Coronavirus Disease 2019 Laboratory Testing Services," July 2, 2021
(e) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 22) – Department of Defense Guidance for Coronavirus Disease 2019 Surveillance and Screening Testing," July 21, 2021
(f) DoD Coronavirus Task Force Diagnostics and Testing Lead Memorandum, "Optimization of Coronavirus Disease 2019 (COVID-19) Testing Resources," March 8, 2021
(g) Acting Under Secretary of Defense for Personnel and Readiness Memorandum, "Force Health Protection Guidance (Supplement 18) – Department of Defense Guidance for Protecting All Personnel in Department of Defense Workplaces During the Coronavirus Disease 2019 Pandemic," March 17, 2021
(h) Office of the Under Secretary of Defense (Comptroller)/Chief Financial Officer of the Department of Defense, "DoD Response to the Novel Coronavirus – Cost Reporting Guidance," April 13, 2020

This memorandum provides guidance for implementing additional force health protection and workplace safety measures directed by the White House Safer Federal Workforce Task Force (reference (a)) to reduce the transmission of the virus that causes the coronavirus disease 2019 (COVID-19). In accordance with reference (a), attestation of an individual's status as fully vaccinated or presentation of a recent negative COVID-19 test is a condition of physical access to DoD buildings and DoD-leased spaces in non-DoD buildings in which official DoD business takes place (referred to jointly in this memorandum as "DoD facilities"). These additional

measures are necessary to continue protecting the health of all DoD personnel, the communities we live and work in, and to preserve total force readiness.

This memorandum applies to all individuals issued a credential by DoD that affords the individual recurring access, classified herein as "credentialed recurring access" (CRA) (e.g., Common Access Cardholders), to DoD facilities, and to non-DoD individuals seeking access, one time or recurring, in association with the performance of official DoD business ("official visitors") (e.g., to attend a meeting).

This memorandum does not apply to personnel receiving ad hoc access to DoD facilities (e.g., delivery personnel, taxi services); to individuals who have access to the grounds of, but not into the buildings on, DoD installations[1] (e.g., contract groundskeepers, fuel delivery personnel, household goods transportation personnel); to personnel accessing DoD buildings unrelated to the performance of DoD business (e.g., residential housing); or to personnel accessing DoD facilities to receive a public benefit (e.g., commissary; exchange; public museum; air show; Morale, Welfare, and Recreation resources).

Individuals other than visitors seeking access to facilities located on DoD installations but operated by other Federal Departments and Agencies will follow the policies and procedures of that other Department or Agency. Visitors will follow applicable policies and procedures of both DoD and the Department or Agency they are visiting.

In accordance with reference (b), Service members (Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard) are required to be vaccinated for COVID-19, and therefore are not required to complete a DD Form 3150, "COVID-19 Certification of Vaccination" (Attachments 1 and 2), nor are they subject to the COVID-19 screening testing set forth in this guidance (Attachments 3 and 4). Service members who receive an exemption from the vaccination requirement are subject to COVID-19 screening testing set forth in this guidance.

DoD civilian employees (regardless of whether they are authorized to telework or perform remote work) and DoD contractor personnel with CRA must attest to their vaccination status by completing DD Form 3150. Such civilian employees and contractor personnel who are unvaccinated for COVID-19, as defined in this guidance, or who decline to attest to their COVID-19 vaccination status will be subject to COVID-19 screening testing at least weekly as set forth in this guidance (Attachment 3). Such civilian employees and contractor personnel who refuse required screening testing, will be denied access to DoD facilities. Service members who are not on active duty and who also hold a DoD civilian personnel position or who are DoD contractor personnel are subject to the requirements in this paragraph.

[1] For the purpose of this memorandum, a DoD installation is a base, camp, post, station, yard, center, homeport facility for any ship, or other area under the jurisdiction of the Secretary of a Military Department or the Secretary of Defense, including any leased location, or in the case of an activity in a foreign country, any area under the operational control of the Secretary of a Military Department or the Secretary of Defense, without regard to the duration of operational control.

Official visitors will be asked to complete DD Form 3150. Official visitors who are unvaccinated, as defined in this guidance, or who decline to volunteer their vaccination status, must show an electronic or paper copy of negative results from a COVID-19 test administered no earlier than 3 days prior to their visit. If an official visitor is unable to show a negative COVID-19 test result, the visitor may be provided onsite self-testing, if available, or will be denied access to the DoD facilities to which access is sought. Service members who are not on active duty at the time of their visit are subject to the requirements in this paragraph.

Heads of DoD Components, the Director of Administration and Management (for the Office of the Secretary of Defense Components, the Chairman of the Joint Chiefs of Staff, the Defense Agencies, and DoD Field Activities), and the Commanders of the Combatant Commands will:

- publish any necessary supplemental instructions and begin implementing the attestation requirements of this memorandum no later than September 13, 2021, followed by implementation of the screening testing requirements based on the availability of testing supplies; and

- ensure that all contract and associated funding implications are considered.

DoD Components should engage with employee unions at their earliest opportunity as they develop agency-specific testing plans and otherwise satisfy any applicable collective bargaining obligations under the law at the earliest convenience, including on a post-implementation basis where appropriate.

This memorandum and other COVID-19 guidance memoranda are centrally located at: **https://www.defense.gov/Explore/Spotlight/Coronavirus/Latest-DOD-Guidance/**.

My point of contact for this guidance is Mr. Steven P. Jones, at (703) 681-7335 or steven.p.jones10.civ@mail.mil.

Gilbert R. Cisneros, Jr.

Attachments:
As stated

ATTACHMENT 1
Determining COVID-19 Vaccination Status

1. **Privacy:**
   a. Medical and other information collected from individuals, including vaccination information and test results, will be treated in accordance with applicable laws and policies on privacy, including the Privacy Act of 1974 and DoD Instruction 5400.11, "DoD Privacy and Civil Liberties Programs," January 29, 2019 (reference (c)).
   b. Such information, including vaccination status, will be accessible only to authorized DoD personnel who have a need to access the record in the performance of their duties to implement the guidance in this memorandum. DoD Components are advised to consult their Component Privacy Officer if there is a need to share this information outside of DoD.
2. **Determining Vaccination Status for the Purpose of this Guidance:**
   a. An individual will be considered "fully vaccinated" when:
      i. at least 2 weeks have elapsed after a second dose in a two-dose COVID-19 vaccine series, such as of the Pfizer-BioNTech/Comirnaty or Moderna COVID-19 vaccines; or at least 2 weeks have elapsed after a single-dose COVID-19 vaccine, such as Johnson & Johnson's Janssen COVID-19 vaccine. The vaccine may be either authorized for emergency use or fully approved; or
      ii. he or she has completed the recommended dose series of COVID-19 vaccines authorized for emergency use by the World Health Organization (e.g., AstraZeneca/Oxford).
   b. "Unvaccinated" will apply to an individual who either:
      i. has not completed the full COVID-19 vaccination dose series; or
      ii. declines to attest to his or her COVID-19 vaccination status.
   c. Completion of DD Form 3150, "Certificate of Vaccination" (Attachment 2):
      i. Individuals with access to Milconnect (**https://milconnect.dmdc.osd.mil/**) should complete the DD Form 3150 via Milconnect; otherwise use of other means is acceptable.
      ii. For Service members (Armed Forces under DoD authority on active duty or in the Ready Reserve, including the National Guard), commanders will determine the COVID-19 vaccination status of their Service members by accessing the Service-specific Individual Medical Readiness (IMR) system. If a Service member has been vaccinated outside the Military Health System, that Service member must show written proof of his or her COVID-19 vaccination status to update the IMR system.
      iii. For DoD civilian employees (including onsite local national employees and Service members not on active duty who are DoD civilian employees):
         - DoD civilian employees will complete DD Form 3150 and provide an electronic copy or hard copy to the appropriate commander or supervisor.
         - The appropriate commander or supervisor will maintain or access the completed DD Form 3150 in accordance with applicable law and policy, including appropriate privacy protection measures. (See paragraph 1 of this attachment).

iv. For DoD contractor personnel with CRA (including Service members not on active duty who are employees of DoD contractors):
    - DoD contractor personnel will complete DD Form 3150; and
    - Maintain a copy of the completed DD Form 3150 and show it to authorized DoD personnel, upon request.
    - Failure to complete the DD Form 3150 may result in denial of access to the DoD facility to which access is sought.

v. For official visitors (including Service members not on active duty):
    - Official visitors will complete DD Form 3150; and
    - Maintain a copy of the completed DD Form 3150 and show it to authorized DoD personnel, upon request.
    - Failure to complete the DD Form 3150 may result in denial of access to the DoD facility to which access is sought.

ATTACHMENT 2
DD Form 3150 – "Certification of Vaccination"

CUI (when filled in)

CERTIFICATION OF VACCINATION	*OMB No. 0704-0613* *Expiration: 20220228*

AGENCY DISCLOSURE NOTICE

The public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dod-informationcollections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

PRIVACY ACT STATEMENT

Authority: DoD is authorized to collect the information on this form pursuant to Executive Order (E.O.) 13991, Protecting the Federal Workforce and Requiring Mask-Wearing and E.O. 12196, Occupational Safety and Health Program for Federal Employees; as well as 10 U.S.C. 113, 10 U.S.C. 136, 10 U.S.C. 7013, 10 U.S.C. 8013, 10 U.S.C. 9013, 10 U.S.C. 2672, 5 U.S.C. chapters 11, and 79, and DoD Instruction 6200.03.
Principal Purpose: This information is being collected and maintained to implement Coronavirus Disease 2019 (COVID-19) workplace safety plans, including DoD's COVID-19 testing programs, and to ensure the safety and protection of the DoD workforce, workplace, and other DoD facilities and environments, consistent with the above-referenced authorities, the COVID-19 Workplace Safety: Agency Model Safety Principles established by the Safer Federal Workforce Task Force, and guidance from the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration.
Routine Use(s): While the information requested on this form is intended to be used primarily for internal purposes, in certain circumstances it may be necessary to disclose this information externally, for example to disclose information to: a person, organization, or governmental entity as necessary and relevant to notify them of, respond to, or guard against a public health emergency or other similar crisis, including to comply with laws governing the reporting of communicable disease or other laws concerning health and safety in the work environment; adjudicative bodies (e.g., the Merit System Protection Board), arbitrators, and hearing examiners to the extent necessary to carry out their authorized duties regarding Federal employment; contractors, grantees, experts, consultants, students, and others as necessary to perform their duties for the Federal government; agencies, courts, and persons as necessary and relevant in the course of litigation, and as necessary and in accordance with requirements for law enforcement; or to a person authorized to act on your behalf. A complete list of routine uses may be found in the applicable System of Records Notice (SORN) associated with the collection of this information. For most Federal employees: OPM/GOVT-10, Employee Medical File System of Records, 75 Fed. Reg. 35099 (Jun. 21, 2010), amended 80 Fed. Reg. 74815 (Nov. 30, 2015). For Federal employees not covered by OPM/GOVT-10, contractor personnel, and other DoD-affiliated persons: DPR 39 DoD, DoD Personnel Accountability and Assessment System of Records,
85 Fed. Reg. 17047 (Mar. 26, 2020) (also available at https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/OSDJS/DPR-39-DoD.pdf).
Consequences of Failure to Provide Information: Providing this information is voluntary. However, if you fail to provide this information, you will be treated as not fully vaccinated for purposes of implementing safety measures, including with respect to mask-wearing, physical distancing, testing, travel, quarantine, and restrictions on access to DoD facilities and environments. Failure to provide such information may also hinder DoD's ability to implement COVID-19 workplace safety plans, thereby increasing the health or safety risk to DoD-affiliated personnel and DoD facilities.

INSTRUCTIONS: This form should be completed by civilian employees, onsite contractor employees, and other individuals if required in accordance with current DoD Force Health Protection Guidance. Service members should not complete this form.

1. NAME *(Last, First, MI)*:	**2. DoD ID NUMBER:**

3. PLEASE CHECK THE BOX BELOW THAT COINCIDES WITH YOUR COVID-19 VACCINATION STATUS :

☐ I am fully vaccinated.
Individuals are considered "fully vaccinated" two weeks after completing the second dose of a two-dose COVID-19 vaccine (e.g., Pfizer-BioNTech or Moderna) or two weeks after receiving a single dose of a one-dose vaccine (e.g., Johnson & Johnson/Janssen).

☐ I am not yet fully vaccinated. I received my first dose of Moderna or Pfizer and my second appointment is scheduled, or I received my final dose of any vaccine less than two weeks ago.

☐ I have not been vaccinated.

☐ I decline to respond.

Individuals who choose not to complete the form will be assumed to be not fully vaccinated for purposes of application of the safety protocols. If you are not vaccinated due to medical or religious reasons, please check either "I have not been vaccinated" or "I decline to respond." Note that if you have already received one dose of a vaccine, but are not yet fully vaccinated, or if you received your final dose less than two weeks ago, then you will be treated as not fully vaccinated until you are at least two weeks past your final dose and resubmit your vaccination information.

☐ I attest that the information provided in this form is accurate and true to the best of my knowledge.

I understand that a knowing and willful false statement on this form can be punished by fine or imprisonment or both (18 U.S.C. 1001). Checking "I decline to respond" does not constitute a false statement. I understand that making a false statement on this form could result in additional administrative action including an adverse personnel action up to and including removal from my position.

4. DATE *(YYYYMMDD)*	**5. SIGNATURE *(Full Name)***

DD FORM 3150, SEP 2021 **CUI (when filled in)**

Controlled by: OUSD(P&R)
Controlled by: ASD(HA)
CUI Category: HLTH: PRVCY; OPSEC
LDC: DL(DoD Only)
POC: osd.pentagon.ousd-p-r.mbx.forms@mail.mil

ATTACHMENT 3
COVID-19 Screening Testing Requirements for DoD Civilian Employees and DoD Contractor Personnel with CRA

1. For DoD civilian employees and DoD contractor personnel with CRA who attest that they are fully vaccinated for COVID-19 using the DD Form 3150, COVID-19 screening testing under this policy is not required. COVID-19 screening testing may be required or offered pursuant to references (d)–(f) regardless of vaccination status.
2. For DoD civilian employees and DoD contractor personnel with CRA, DoD Components will:
    a. execute the screening testing requirement with COVID-19 self-collection kits or self-tests at least weekly that can be performed primarily onsite on the installation or facility with proper supervision and documentation of testing results. If onsite COVID-19 screening testing is not feasible, as an alternative the self-testing can be performed at home or in other locations (Note: these COVID-19 self-tests do not require a health care provider's clinical care order and are, therefore, considered an over-the-counter test and do not require medical support to complete);
    b. procure and provide these COVID-19 self-tests and establish guidance for where and how these tests will be distributed and conducted and how results are to be reported.
        i. DoD civilian employees are responsible for providing documentation of negative COVID-19 test results, upon receipt, to the appropriate commander or supervisor. DoD civilian employees may not be required to use their own personal equipment for the purpose of documenting test results; offsite tests may not be used if there is not a means to document results using government equipment. The commander or supervisor is responsible for maintaining any COVID-19 test results provided by DoD civilian employees in accordance with applicable law and policy, including appropriate privacy protection measures (See paragraph 1 of Attachment 1).
        ii. DoD contractor personnel with CRA will maintain a copy of their most recent COVID-19 test result and show such results to authorized DoD personnel, upon request.
3. After screening testing procedures are established, for COVID-19 unvaccinated DoD civilian employees and contractor personnel with CRA entering a DoD facility, COVID-19 screening testing with a Food and Drug Administration (FDA) authorized or approved test is required and a negative COVID-19 screening test result is required for entry into the worksite in the DoD facility. If the COVID-19 screening test is administered offsite, the negative result must be from a test performed in the past 3 days. If the negative result is over 3 days old, a new test is required.
4. DoD civilian employees and contractor personnel with CRA who have positive COVID-19 screening tests will be required to remain away from the workplace in accordance with reference (g). DoD civilian employees, and DoD contractor personnel with CRA with positive COVID-19 screening tests will be offered, but are not required to take, confirmatory laboratory-based molecular (i.e., polymerase chain reaction) testing paid for by their DoD Component. If the confirmatory test is negative, the individual is not COVID-19 positive and will be allowed into the workplace. Contact tracing will be conducted in accordance with references (d) and (e).

5. For DoD civilian employees, COVID-19 screening testing is expected to take no more than 1 hour of regular duty time, per test, to complete required testing as directed by the DoD Component. This includes time for travel to the testing site, time to complete testing, and time to return to work. Laboratory-based confirmatory COVID-19 testing for initial positive screening test results is expected to take no more than 2 hours of duty time. Commanders and supervisors will monitor duty time usage and keep duty time used for testing within these parameters to the extent possible.
6. Refusal of COVID-19 testing by unvaccinated DoD civilian employees:
    a. DoD Components may initiate adverse employment action, up to and including removal, against unvaccinated civilian employees who refuse COVID-19 testing.
    b. DoD Components may bar such employees from their worksites on the installation or facility to protect the safety of others, including while adverse action is pending. While barred from their worksites on the installation or facility, such employees may be required to telework or will be placed on administrative leave, as appropriate.
    c. A religious or medical exemption from COVID-19 vaccination is not an exemption from the COVID-19 testing required by this policy. If a DoD civilian employee requires a religious or medical exemption from participation in COVID-19 screening tests, DoD Components should follow existing processes to determine if an appropriate flexibility or accommodation may be provided.

ATTACHMENT 4
Requirements for Obtaining Self-Collection Kits and Self-Tests

1. COVID-19 self-tests must have Instructions for Use and FDA Approval, 510(K) clearance or have an FDA Emergency Use Authorization, and will be made available through the Defense Logistics Agency.
2. Cost reporting for the purchase of testing materials or reimbursement for member tests should be in accordance with reference (h).
3. Funding for COVID-19 testing: If self-collection kits or self-tests are not available:
    a. DoD Components are responsible for funding required COVID-19 screening tests.
    b. Each DoD Component will establish procedures to reimburse Service members and DoD civilian employees for COVID-19 screening tests that require payment for purposes of meeting the screening testing requirement (e.g., if the screening test is not available through the DoD Component and must be administered by a facility who charges for the test).
    c. For COVID-19 testing of DoD contractor employees with CRA, DoD Components will offer COVID-19 testing similar to that offered to DoD civilian employees at the DoD Component's expense and at no cost to the employee or their employer.

PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

APR 1 4 2021

MEMORANDUM FOR SENIOR PENTAGON LEADERSHIP
COMMANDERS OF THE COMBATANT COMMANDS
DEFENSE AGENCY AND DOD FIELD ACTIVITY DIRECTORS

SUBJECT: Administrative Leave for Coronavirus Disease 2019 Vaccination of Department of Defense Employees

Reference: Executive Order 13991, "Protecting the Federal Workforce and Requiring Mask-Wearing," January 20, 2021

The Coronavirus Disease 2019 (COVID-19) continues to present risk to the health and welfare of our DoD civilian workforce. The reference established the Safer Federal Workforce Task Force, which has encouraged the prioritization, distribution, and administration of the vaccination to Federal employees. To safeguard our DoD civilian workforce and to limit the spread of COVID-19, DoD employees who are authorized to be absent from duty for purposes of receiving a COVID-19 vaccination shall be granted administrative leave.

Supervisors shall grant employees up to 4 hours of administrative leave, per vaccination event, to receive COVID-19 vaccinations administered by DoD, Federal, State and local government organizations, or private health care organizations and pharmacies. The use of administrative leave is limited to time spent traveling to and from the vaccination location, time at the vaccination location, and, if needed, for a reasonable amount of recovery time. Generally, employees should not require more than two vaccination events to complete a vaccination series, or more than 4 hours of administrative leave for each event. On a case-by-case basis, supervisors may grant employees who encounter extenuating circumstances additional administrative leave. For employees who experience an adverse reaction to a COVID-19 vaccination, no more than 2 workdays of administrative leave should be granted for recovery associated with a single vaccination dose. Employees may not be authorized to perform overtime work for purposes of receiving a vaccination outside their scheduled tour of duty. Components shall comply with applicable collective bargaining obligations, as appropriate.

A reference guide containing frequently asked questions and answers is attached. For more information, my point of contact is Ms. Melissa Lalonde, Associate Director, Employment and Compensation, Defense Civilian Personnel Advisory Service (DCPAS), at (571) 372-1557 or melissa.a.lalonde.civ@mail.mil. For Nonappropriated Fund (NAF)-related issues, my point of contact is Ms. Itzel Santana, Associate Director, NAF Personnel Policy, DCPAS, at (571) 372-1565 or itzel.r.santana.civ@mail.mil.

Virginia S. Penrod

Virginia S. Penrod
Acting

Attachment:
As stated

Q11. What time and attendance code should employees use to document administrative leave used for a COVID-19 vaccination event and recovery?

A11. Employees should use the time and attendance code for "physical fitness" to record administrative leave for COVID-19 vaccinations and recovery. The type hour code is 'LN' and the environmental/hazard/other code is 'PF'. Nonappropriated fund employers should code administrative leave for COVID-19 vaccinations in a way that can be easily reported.

Q12. May **a supervisor ask employees if they have been vaccinated for COVID-19?**

A12: For purposes of acting on a request for administrative leave for vaccination and recovery, supervisors may ask employees about the time and location of the vaccination event and whether there was a reaction to the vaccine requiring a period of recovery. But as a general matter, supervisors may not ask employees if they have been vaccinated. Supervisors may ask about an employee's vaccination status only if there is a business necessity for this information, as determined on a case-by-case basis. Currently, COVID-19 vaccines have been approved under an Emergency Use Authorization and vaccination has not been established as a requirement through appropriate DoD processes for any DoD civilian occupation. Therefore, the information is not necessary for purposes of most employment decisions. In particular, information about an employee's vaccination status is not necessary for supervisors to make decisions about how and when employees will report to a workplace instead of telework. Supervisors need to follow applicable Force Health Protection guidance and implement appropriate workplace measures to protect all employees, assuming that not everyone will be vaccinated. Only in very limited circumstances, such as determining how long an employee with a known or suspected exposure must temporarily remain out of the workplace or whether an employee may be exempted from certain force health protection requirements as authorized in applicable policy, would it be reasonably necessary to request an employee voluntarily provide information about the employee's vaccination status. Such information would be obtained on a case-by-case basis, to comply with specific Force Health Protection guidance, not as part of a general survey of the workforce.

Q13. May the human resources or occupational health office ask employees if they would like to be offered an employer-provided vaccination?

A13: Yes. The human resources or occupational health office may survey the workforce to determine employee interest in receiving an employer-provided vaccination for purposes of obtaining an appropriate number of doses and facilitating voluntary vaccination. The surveying office may not make assumptions about the vaccination status of employees who do or do not express interest in an employer-provided vaccination. A list of interested employees should not be retained once it has served its intended purpose of facilitating voluntary participation in employer-provided vaccination clinics. Only the minimum amount of personally identifiable information (PII) needed to determine employee interest in receiving the vaccine and to inform the number of doses required to meet demand at each vaccine tier level should be collected; no information concerning a person's medical condition may be requested or maintained for such purposes. PII collected during such a survey must be appropriately safeguarded. Additionally, any PII compiled in response to the data call must be shared only with those who have an official need to know because an individual's vaccine tier may potentially reveal the person has a medical condition.

Chris Kroenung
Response to Notice of proposed removal
November 4, 2022

1. Testing is discriminatory. Testing only "unvaccinated" is not only unfair it has been widely proven that all three of the vaccines have low efficacy rates and are practically ineffective within six months. Most people started getting "vaccinated" back in February of 2021 which would mean most of the "vaccines" would be ineffective sometime between August and January 2022. Also there have been many "breakthrough" cases which proves that testing less than 10% of the workforce is ineffective, a waste of time and a waste of money.

2. The current presidential administration, and OPM, recommended starting testing on Feb 15, 2022. NGA began testing on Dec 13, 2021. Why was this done? Why the Rush? Was this necessary to try to please someone at a higher level. Moving this date makes no sense and shows that the current NGA administration only wants 100% compliance for the "vaccine".

3. I requested to take sick leave for the time that I was out and I was denied. I requested to take Annual leave during this time and was denied. I requested to telework during this time and was denied. I also requested LWOP and was denied. Why deny people leave if this "pandemic" is so serious? This is an abuse of authority to try to coerce NGA employees to take an experimental "vaccine" against there will

4. All test swabs are tainted with Ethylene Oxide. Ethylene Oxide is a carcinogen as defined by the FDA and the CDC. EO also has an OSHA fact sheet that lists it as chemical that causes cancer. I understand there is only a trace amount in each swab but as far as I have read the tests were never meant to be given weekly only when someone is symptomatic (maybe up to four times per year). No studies have been done to determine the amount of test taken to be dangerous. Is it 10, 20, 50 only time and people getting sick will tell.

5. Forced testing and "vaccination" is a violation of the ADA. Any medical examination must be job related, consistent with business necessity, and conducted by a health care professional. Since we should have leave, teleworking and LWOP available the covid testing does not meet the business necessity requirement, and I do not see any way that participating in experimental covid testing is job related. I know the EEOC has approved testing and glossed over the ADA but the ADA was voted on by congress the EEOC are not elected officials and should not be interpreting law without some level of judicial oversight.

6. Covid testing, and "vaccination" has become a political football. I come in every day to work not to be used as pawn for political gain.

7. The omicron variant presented itself in November of 2021. The Omicron variant is a very weak variant that removes a good portion of the "danger" that "vaccination" and covid testing are supposed to prevent. How much longer will this "pandemic" go on? How long will NGA employees have to test for a virus that is no more dangerous than the common cold?

8. CDC guidelines for medium and high levels are to get tested if you have symptoms and to stay up to date with covid "vaccines". These recommendations are not being followed by NGA. Why the contradiction? NGA claims to follow CDC guidelines as a reason for the restrictions? It seems to me that CDC guidelines do not really matter that only compliance to an unenforceable "vaccine" mandate is the only thing that matters.

9. CDC guidelines changed on Aug. 11, they claimed you could no longer discriminate based on vaccination status(because the vaccinated can get the virus and can transmit the virus). The Safer Federal Workforce Taskforce required all government agencies to change their policies to reflect this guidance. To this day DOD policy has not changed. Several Agencies have changed their polices to reflect the new CDC guidelines USDA, GSA, and HHS to name a few. The fact is the CDC has known this that the vaccinated can contract the virus and transmit the virus for a long time and soon I will have the FOIA data to prove this.

10. Please send me a response to all of these points.

You have accessed part of a historical collection on war.gov. Some of the information contained within may be outdated and links may not function. Please contact the DOW Webmaster with any questions.

TRANSCRIPT

Pentagon Press Secretary John F. Kirby Holds a Press Briefing

Aug. 9, 2021

Pentagon Press Secretary John F. Kirby

PRESS SECRETARY JOHN F. KIRBY: So a few things off the top. Bear with me. OK, I think you've seen by now the Secretary's memo to the -- message to the force about COVID vaccines. That -- that's public now, so I'm not going to re-read it for you. I think you all can get the gist of it.

I would just point out that there's sort of three elements here to it. One is that -- that he will -- it -- request approval from the President for a waiver to make the COVID vaccines mandatory by mid-September -- he'll make the request for the waiver by mid-September.

I've seen some reporting out there that that means that all of the troops have to be vaccinated by mid-September. That's not accurate. He'll make the request by mid-September, unless or until FDA licensure occurs before that time, at which point the Secretary has the authority he needs, upon FDA licensure, to issue -- to make whatever vaccine is then given that license mandatory. I just want to clear that up. That's point number one.

Q: Hi, thanks. So, how is the service going to track compliance for the COVID vaccine and verify that people who got the shot elsewhere, like not in a military facility like guardsmen and reservists, have actually been vaccinated and aren't just claiming that they did? My second question is, what are the consequences going to be for those who don't? Who continues to refuse to get the shot? Is this going to be punished like a refusal to obey a lawful order?

MR. KIRBY: So, I think the first question you're referring to is what the interim between now and when it's mandatory? Because once the vaccine is mandatory, your -- your inoculations go into your electronic medical records. So, it's -- it's documented that way. So, if you're talking about what's gonna happen between now and then, as I said, at the very beginning of the press conference, we are working through what will be a policy directive to the services to lay it out for them. What do the new restrictions and requirements ordered by the President, what does that mean for uniformed personnel? So, I just don't have that answer right now.

Your second question is about -- I'm guessing what you're talking about is, once the vaccines are mandatory, and if a member were to refuse after it became an order, a lawful order? I'm not going to speculate and get into hypotheticals right now, but I think you saw in the Secretary's memo of today that -- that he has full confidence that service leadership and commanders are going to implement the new vaccination program with professionalism, skill, and with compassion. And I think I'd leave it -- leave it at that for now. OK, back to the room?

Q: What is the actual deadline for the service leadership to get their plans to the Secretary?

MR. KIRBY: He did not issue a specific deadline in this memo. They were already -- some of them were already working on the potential because all of us had a sense that this was coming. But he did not give them an actual deadline. He does not expect that it's going to take them very long to come back with implementation plans. But he wants those implementation plans ready before -- certainly before the -- the middle of September. Obviously, we'd like to see those plans submitted earlier than that because it's possible that we could reach FDA licensure on at least one vaccine, perhaps as early as the end of the month. He met with the service secretaries this morning; they all understand the timing

here. And the Secretary is not worried about them meeting a certain deadline on the calendar; they all know what they have to do in the timeframe within which they have to do it.

Q: Follow up, given there's already kind of an accountability infrastructure for ongoing vaccines while you're in uniform. What needs to be hammered out? Flu vaccines are given every year; there's an accountability, you know, that's -- that's in the computer if you don't get your flu vaccine, there are already consequences. So, what needs to be hammered out when this infrastructure already exists?

MR. KIRBY: Adding a vaccine to the mandatory list doesn't -- doesn't happen every day. It's a -- it's a big muscle movement. And the Secretary wants to give the services ample time to prepare for that, as well as the force. I mean, this has been -- as you and I have gone back and forth here for months, I mean, it's been a voluntary vaccine from the -- from as soon as the time that we had them. And -- and now shifting to making it -- eventually making it a mandatory vaccine, a required vaccine, that's a big shift. Not just for the system and our military treatment facilities but also for the force itself. And you can consider this memo today as what we would call in the military a warning order. A warning order to the force that this is coming, and we want you to be ready for it as well. And obviously, we'd prefer that in -- that -- that you get the vaccine now and not wait for the mandate.

Q: So, that mid-September date then, is that more trying to line up with these FDA approvals given that you don't think that it's going to take very long for plans to be put together? And the Secretary is not going to take very long to approve those plans. Why wait more than a month to get this?

MR. KIRBY: Again, we -- we think that FDA licensure will probably occur at least in one case sooner than that. And this was really determined to give enough time and space for the force a very geographically dispersed operationally able and out their force to get ready for the potential mandatory issuance of this vaccine. It -- it was in the Secretary's determination, an ample amount of time to prepare, keeping in mind that we may have to move sooner based on FDA approval with the Secretary has approval authority once FDA -- FDA licensure occurs. So, it was a combination of factors. OK?

Q: I got a bunch. OK, so...

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SEPTEMBER 09, 2021

Remarks by President Biden on Fighting the COVID-19 Pandemic

5:02 P.M. EDT

THE PRESIDENT: Good evening, my fellow Americans. I want to talk to you about where we are in the battle against COVID-19, the progress we've made, and the work we have left to do.

And it starts with understanding this: Even as the Delta variant 19 [sic] has — COVID-19 — has been hitting this country hard, we have the tools to combat the virus, if we can come together as a country and use those tools.

If we raise our vaccination rate, protect ourselves and others with masking and expanded testing, and identify people who are infected, we can and we will turn the tide on COVID-19.

It will take a lot of hard work, and it's going to take some time. Many of us are frustrated with the nearly 80 million Americans who are still not vaccinated, even though the vaccine is safe, effective, and free.

You might be confused about what is true and what is false about COVID-19. So before I outline the new steps to fight COVID-19 that I'm going to be announcing tonight, let me give you some clear information about where we stand.

First, we have cons- — we have made considerable progress in battling COVID-19. When I became President, about 2 million Americans were fully vaccinated. Today, over 175 million Americans have that protection.

Before I took office, we hadn't ordered enough vaccine for every American. Just weeks in office, we did. The week before I took office, on January 20th of this year, over 25,000 Americans died that week from COVID-19. Last week, that grim weekly toll was down 70 percent.

And in the three months before I took office, our economy was faltering, creating just 50,000 jobs a month. We're now averaging 700,000 new jobs a month in the past three months.

This progress is real. But while America is in much better shape than it was seven months ago when I took office, I need to tell you a second fact.

We're in a tough stretch, and it could last for a while. The highly contagious Delta variant that I began to warn America about back in July spread in late summer like it did in other countries before us.

While the vaccines provide strong protections for the vaccinated, we read about, we hear about, and we see the stories of hospitalized people, people on their death beds, among the unvaccinated over these past few weeks.

This is a pandemic of the unvaccinated. And it's caused by the fact that despite America having an unprecedented and successful vaccination program, despite the fact that for almost five months free vaccines have been available in 80,000 different locations, we still have nearly 80 million Americans
who have failed to get the shot.

And to make matters worse, there are elected officials actively working to undermine the fight against COVID-19. Instead of encouraging people to get vaccinated and mask up, they're ordering mobile morgues for the unvaccinated dying from COVID in their communities. This is totally unacceptable.

Third, if you wonder how all this adds up, here's the math: The vast majority of Americans are doing the right thing. Nearly three quarters of the eligible have gotten at least one shot, but one quarter has not gotten any. That's nearly 80 million Americans not vaccinated. And in a country as large as

ours, that's 25 percent minority. That 25 percent can cause a lot of damage — and they are.

The unvaccinated overcrowd our hospitals, are overrunning the emergency rooms and intensive care units, leaving no room for someone with a heart attack, or ~~pancreitis~~ [pancreatitis], or cancer.

And fourth, I want to emphasize that the vaccines provide very strong protection from severe illness from COVID-19. I know there's a lot of confusion and misinformation. But the world's leading scientists confirm that if you are fully vaccinated, your risk of severe illness from COVID-19 is very low.

In fact, based on available data from the summer, only one of out of every 160,000 fully vaccinated Americans was hospitalized for COVID per day.

These are the facts.

So here's where we stand: The path ahead, even with the Delta variant, is not nearly as bad as last winter. But what makes it incredibly more frustrating is that we have the tools to combat COVID-19, and a distinct minority of Americans –supported by a distinct minority of elected officials — are keeping us from turning the corner. These pandemic politics, as I refer to, are making people sick, causing unvaccinated people to die.

We cannot allow these actions to stand in the way of protecting the large majority of Americans who have done their part and want to get back to life as normal.

As your President, I'm announcing tonight a new plan to require more Americans to be vaccinated, to combat those blocking public health.

My plan also increases testing, protects our economy, and will make our kids safer in schools. It consists of six broad areas of action and many specific measures in each that — and each of those actions that you can read more about at WhiteHouse.gov. WhiteHouse.gov.

The measures — these are going to take time to have full impact. But if we

implement them, I believe and the scientists indicate, that in the months ahead we can reduce the number of unvaccinated Americans, decrease hospitalizations and deaths, and allow our children to go to school safely and keep our economy strong by keeping businesses open.

First, we must increase vaccinations among the unvaccinated with new vaccination requirements. Of the nearly 80 million eligible Americans who have not gotten vaccinated, many said they were waiting for approval from the Food and Drug Administration — the FDA. Well, last month, the FDA granted that approval.

So, the time for waiting is over. This summer, we made progress through the combination of vaccine requirements and incentives, as well as the FDA approval. Four million more people got their first shot in August than they did in July.

But we need to do more. This is not about freedom or personal choice. It's about protecting yourself and those around you — the people you work with, the people you care about, the people you love.

My job as President is to protect all Americans.

So, tonight, I'm announcing that the Department of Labor is developing an emergency rule to require all employers with 100 or more employees, that together employ over 80 million workers, to ensure their workforces are fully vaccinated or show a negative test at least once a week.

Some of the biggest companies are already requiring this: United Airlines, Disney, Tysons Food, and even Fox News.

The bottom line: We're going to protect vaccinated workers from unvaccinated co-workers. We're going to reduce the spread of COVID-19 by increasing the share of the workforce that is vaccinated in businesses all across America.

My plan will extend the vaccination requirements that I previously issued in the healthcare field. Already, I've announced, we'll be requiring vaccinations that all nursing home workers who treat patients on Medicare and Medicaid,

because I have that federal authority.

Tonight, I'm using that same authority to expand that to cover those who work in hospitals, home healthcare facilities, or other medical facilities –- a total of 17 million healthcare workers.

If you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period.

Next, I will sign an executive order that will now require all executive branch federal employees to be vaccinated — all. And I've signed another executive order that will require federal contractors to do the same.

If you want to work with the federal government and do business with us, get vaccinated. If you want to do business with the federal government, vaccinate your workforce.

And tonight, I'm removing one of the last remaining obstacles that make it difficult for you to get vaccinated.

The Department of Labor will require employers with 100 or more workers to give those workers paid time off to get vaccinated. No one should lose pay in order to get vaccinated or take a loved one to get vaccinated.

Today, in total, the vaccine requirements in my plan will affect about 100 million Americans –- two thirds of all workers.

And for other sectors, I issue this appeal: To those of you running large entertainment venues — from sports arenas to concert venues to movie theaters — please require folks to get vaccinated or show a negative test as a condition of entry.

And to the nation's family physicians, pediatricians, GPs — general practitioners –- you're the most trusted medical voice to your patients. You may be the one person who can get someone to change their mind about being vaccinated.

Tonight, I'm asking each of you to reach out to your unvaccinated patients

over the next two weeks and make a personal appeal to them to get the shot. America needs your personal involvement in this critical effort.

And my message to unvaccinated Americans is this: What more is there to wait for? What more do you need to see? We've made vaccinations free, safe, and convenient.

The vaccine has FDA approval. Over 200 million Americans have gotten at least one shot.

We've been patient, but our patience is wearing thin. And your refusal has cost all of us. So, please, do the right thing. But just don't take it from me; listen to the voices of unvaccinated Americans who are lying in hospital beds, taking their final breaths, saying, "If only I had gotten vaccinated." "If only."

It's a tragedy. Please don't let it become yours.

The second piece of my plan is continuing to protect the vaccinated.

For the vast majority of you who have gotten vaccinated, I understand your anger at those who haven't gotten vaccinated. I understand the anxiety about getting a "breakthrough" case.

But as the science makes clear, if you're fully vaccinated, you're highly protected from severe illness, even if you get COVID-19.

In fact, recent data indicates there is only one confirmed positive case per 5,000 fully vaccinated Americans per day.

You're as safe as possible, and we're doing everything we can to keep it that way — keep it that way, keep you safe.

That's where boosters come in — the shots that give you even more protection than after your second shot.

Now, I know there's been some confusion about boosters. So, let me be clear: Last month, our top government doctors announced an initial plan for booster shots for vaccinated Americans. They believe that a booster is likely

FDA Virtual Town Hall Series – Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests

Moderator: Irene Aihie
March 17, 2021
12:15 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the Q&A session, if you'd like to ask a question you may press star 1 on your phone. Today's call is being recorded. If you have any objections you may disconnect at this time. I'd like to turn the call over to Ms. Irene Aihie. You may begin.

Irene Aihie: Thank you. Hello. I am Irene Aihie of CDRH's Office of Communications and Education. Welcome to the FDA's 47th in a series of virtual town hall meetings to help answer technical questions about the development and validation of tests for SARS-CoV-2 during the public health emergency.

Today Toby Lowe, Associate Director of the Office of In Vitro Diagnostics and Radiological Health, and Dr. Timothy Stenzel, Director of the Office of In Vitro Diagnostics and Radiological Health in the Office of Product Evaluation and Quality, both from CDRH, will provide a brief update.

Following opening remarks, we will open the line for your questions related to the development and validation of tests for SARS-CoV-2. Please remember that during this town hall we are not able to respond to questions about specific submissions that might be under review. Now I give you Toby.

Toby Lowe: Thanks, Irene. Thanks everyone, for joining today. I have a couple of updates and then I will hand it over to Tim for some more. First, I wanted to make sure everyone was aware that just this morning the updated templates on our Web site, we updated the serology template for test developers. And in that update we added some information about viral mutations and variants, and also did some clarifying edits throughout. So hopefully that will be useful.

And then we also posted a new template for test developers of serology tests that the text will correlate to neutralizing antibodies. So I know we've had a lot of interest in that template and a lot of people waiting for it. So it has been posted and we hope that is still helpful for you.

The other update that I have is that starting tomorrow we will open up the ability for you to send questions by email ahead of time for us to consider prior to the town hall, so that we can try and address potentially more frequently asked questions. So we will be - there will be an email that goes out likely tomorrow, with instructions on how to do that. And the email address will be CDRHWebinars@FDA.HHS.gov. But again, you'll get an email - if you're on the town hall email list you'll get an email with those instructions tomorrow, once that opens up.

And with that, I will turn over to Tim, to give some additional updates.

Dr. Timothy Stenzel: Thank you, Toby and welcome again, today. I am hearing that some callers may be having trouble calling in. So if our technical team could check on that and assist those callers, that would be great. Let me start off with, prior to getting to the main topic, with frequently asked question that we get about the use of frozen bank samples for validation of point of care tests on a particular antigen test.

And yes, we are allowing banked frozen samples to be used and banked samples can be mixed in with fresh samples. We still are asking that at least 10% to 20% of the positives are composed of low positive samples which reflect the natural distribution of SARS-CoV-2 viral loads. We have seen that even early in symptomatic disease that CTs can be relatively high.

Per the antigen template, you know, we do want to see these low positives, at least 10%. You know, and then we do want to see fresh sample as well, a minimum of five positive samples pre-market. And this is because we have noted multiple times now, both for molecular and for antigen, that freezing can actually for still specifically undetermined reasons, allows a greater sensitivity.

And so pre-frost studies can show that the performance is same or different. But just to be safe we do want to see a minimum of five fresh samples pre-market, positive samples. And then we would ask you to fulfill that on the rest of the samples being fresh after authorization.

Okay. With that, I will move into the main topic. So yesterday we issued a new policy, serial screening and particularly screening asymptomatic individuals which we view as a critical part of reducing the spread of COVID-19. You know, screening involves testing asymptomatic individuals who do not have known or suspected exposure to COVID-19 in order to make

individual patient decisions such as whether an individual participates in an activity based on the test results.

Yesterday we also issued a fact sheet to assist schools, workplaces, communities and others, looking to establish blood testing programs to screen asymptomatic individuals as they are selecting a test for screening. We also posted a new template for molecular and antigen tests for serial screening.

We expect that the recommendations and information we provided here for test developers, will help streamline the path to an EUA authorization for screening tests, specifically the template outlines, outline situations in which FDA may authorize certain tests for screening, with serial testing prior to conducting - prior to the developers conducting certain performance evaluations with asymptomatic individuals.

This may include, in certain circumstances, authorizing a point of care and at home tests for OTC, nonprescription use, if all the appropriate studies have been other studies for usability and user studies and user comprehension have been outperformed. In this situation we are leveraging evidence of a test strong performance in symptomatic patients.

Combined with serial testing it mitigates the risk of false results when testing asymptomatic individuals for the cases in which we have not reviewed the asymptomatic testing performance pre-market. And we expect to see that in the post market studies showing and demonstrating adequate performance in the post-market setting would demonstrate that adequate performance with the serial testing plan.

I want to back up a little bit, talk about how important home tests, point of care tests in particular antigen tests are. So starting in January 2020 we - the

FDA and other US government entities reached out to companies that are capable of producing antigen point of care tests and ultimately obviously, home tests which we've authorized.

You know, it wasn't that long to the year that we authorized our first antigen test. And then to date I think we've authorized 15 antigen tests. We are very interested in home use and on July 29, 2020 we issued a template with our recommendations, for home validations so that we can authorize both prescription and over the counter testing.

In September of 2020 in a piece on the Hill, we suggested that for a test that may be performing lower than recommended levels could use serial testing to improve overall performance using the combined results, two or more tests, to be able to achieve, you know, a good level of sensitivity. To date though, we've received no formal EUA submission of a fixed serial testing plan showing that it is functioning.

We hope this - that this new pathway, this new policy will accelerate the use of serial testing to reopen schools and reopen workplaces and other situations and say to keep convalescent settings safe. We recently were - FDA was recently briefed on a very well-designed, well-executed study that used serial testing of an EUA authorized molecular test and an EUA authorized antigen test.

And although it clearly showed that on a head to head competition or comparison, the antigen testing was significantly less sensitive than the molecular test. It also demonstrated that a serial testing program for the antigen test significantly mitigated the risk of false negatives in that serial testing program. So that was sort of the first really firm good evidence that we had and helped usher in this new policy.

So throughout this - throughout the year, last year, we have striven to provide flexibility and adaptability in approaches to validate all tests including home tests, screening tests. So we have authorized a number of screening tests, I think almost a score, and we hope that this greatly accelerates that as well. I wanted to go into a few more details.

You know, CLIA requirements are overseen by CMS and FDA's actions in this policy are not removing any CLIA requirements for the use of at home tests for self-testing in the - is not subject to CLIA requirements. This new template is also not automatically changing any authorizations. It is providing a streamlined path for test developers seeking serial screening claims.

So in order for a test to be authorized for OTC or nonprescription use, such tests need to be - needs to have previously shown asymptomatic screening data. But with this, since - in order to be an OTC test. But now we are allowing that data for asymptomatic performance using screening, to be revealed to us after authorization.

This template provides an option for screening authorization prior to collecting data or submitting - completing the validation for asymptomatic individuals. We would still expect validation symptomatic individuals as well as usability, user comprehension and layperson appropriate labeling for an OTC test.

For a developer who's already submitting that information, they would not need to submit more for FDA to authorize their test for OTC though. They can simply come in with a supplemented amendment application asking to convert to OTC based on the serial testing program.

Of course, the older pathway still exists. If someone comes in with, you know, meeting your performance expectations for an OTC test, on a one time test performance we will continue to authorize that, without the recommendation for serial testing. And that may be still an attractive option. Obviously we've already authorized many OTC collection kits and some OTC home tests.

So - and of course, providers must still order tests that are authorized only for diagnostic purposes and we're not going to object to the off label prescription use of those tests that don't have a screening claim. You know, the FDA does not determine the claims the test developer decides to request for their test or their application.

We are encouraging them to pursue this option if it's applicable to them and they are interested in it. We do authorize tests for certain indications and for certain - use in certain settings as appropriate by their validation. Generally point of care tests are authorized for use in the settings of under CLIA certificate of waiver with healthcare workers that are untrained non-laboratorians.

These tests typically included an instrument and required a trained user to operate them, but not always. And it's not required to have an instrument. CMS is responsible for oversight of CLIA certification. Of course tests that are authorized for at home use are appropriate for self-testing. Without a trained operator it may be used for self-testing at home or self-testing in other settings, such as schools, workplaces, and are not subject to CLIA requirements in that specific narrow self-test category.

Going further, each authorization indicates whether a test is for prescription or nonprescription use. Or as we said before in reiterating the fact sheet, when

we issued yesterday, tests authorized for a symptomatic claim, can be ordered by a provider for screening purposes and I've made that clear earlier in this discussion.

Some entities may use a blanket prescription to cover screening tests for their entire population. And if a test is authorized for OTC, over the counter, no prescription of course, is required. And as we've said previously including our prior FAQ and reiterated in the fact sheet we issued yesterday, you know, clinicians can absolutely order tests for off label use of screening. We're not going to object to that.

It is important however to be aware that certain tests include labeling. And state the tests should only be used for symptomatic individuals. These tests should not be used for screening and they would - this pathway would not be open to them. However, we do know that some groups are setting up testing programs for back to school, back to work, and prefer to use a test that is authorized for screening. That's an important point.

We have definitely heard resistance about using tests off label from some quarters and from some clinicians. And this hopefully paves the way for getting rid of that as an issue. And once we authorize a test for screening they of course are covered by PrEP Act coverage. So again, we hope that this streamlined path will lead to more test developers seeking and receiving a screening claim.

And as we indicated, and this is primarily for antigen tests that will be severely tested multiple times a week, we expect to see a minimum performance sensitivity for symptomatic testing of at least 80% with 70% as the lower bound of the two sided 95% confidence sample, which we believe

offers additional flexibility in obtaining the screening claim and using and including an OTC, over the counter use.

So with that, that was a lot of information, we would like to go ahead and open up this call for questions and we look forward to that. Thank you.

Coordinator: The phone lines are now open for questions. If you would like to ask a question over the phone, please press star 1 and record your name. If you'd like to withdraw your question press star 2. First question in the queue is from Shannon…

Toby Lowe: Okay. Before - sorry, before we take the first question, this is Toby Lowe, I just wanted to jump in with one additional point of clarification. Tim talked about healthcare providers ordering tests off label and since there was quite a bit of discussion about at home testing in that I just want to clarify that a healthcare provider can order a test for a different indication but not - but they cannot order a test for home use if it is not authorized for home use.

Coordinator: And with that, I will turn it back over to you to take the first caller.

Dr. Timothy Stenzel: Yes. I didn't cover that caveat. Thank you, Toby. I appreciate that.

Toby Lowe: Yes.

Coordinator: First question in the queue is from Shannon Clark. Your line is open.

Shannon Clark: Good morning. This is Shannon Clark with UserWise Consulting. We specialize in human factors testing. But I have a question about limited detection determination. So to determine a limit of detection for an antigen test kit, do you have any requirements regarding which strain of inactivated

virus is used to create contrived samples in the calculation of limit of detection?

Can we just use one US strain in order to create the contrived samples and determine the limit of detection?

Dr. Timothy Stenzel: So, you know, for molecular tests I just explained on a (Red X) call earlier this morning, some of them are going to be looking at the use of degenerate primers to make sure that they're covering the various mutations that are in circulation if they cannot engineer the assay around where they want to update their assay to maintain current levels of performance in the face of increasing numbers in locations of mutations.

It could be that in the use of degenerate primers there could be changes in LOD. So we're working through what that might look like. But for antigen tests, I think you're probably asking about for antigen tests, known variants or mutation that could affect the performance of that antigen test. Look to our mutation communication, a recent one, for how we're asking developers to start looking for potential issues with their antigen, molecular or serology tests. But I - yes, at the moment, one stream can be used for LOD determination.

Shannon Clark: Thanks so much.

Coordinator: Next question in the queue is from (Jeff Andrews). Your line is open.

(Jeff Andrews): Hi Dr. Stenzel. Thanks for taking the call. I'd like to confirm that for an EUA antigen test that - in symptomatic has a PPA above 80%, that you are saying that this new template that was released yesterday, will permit authorization for a screening claim and then - in addition to the symptomatic claim. And I

wanted to clarify whether that means that that screening claim for asymptomatics is only with serial testing or would also include one time use and whether a post market study is always required or whether that's a decision the FDA would make individually.

Dr. Timothy Stenzel: Yes. We're anticipating that the serial testing will bring performance in an - unknown performance in asymptomatic population up to an acceptable level. We will want to measure that for each device that - a test that's authorized in a post market study, to confirm the performance in the asymptomatic population reaches that 80% or more, utilizing serial testing.

So yes, a test authorized for - currently authorized for at least 80% sensitivity PPA or above, with the lower bound being 70% or greater, can seek this immediate change to a screening claim at the point of care test. And they've done all of the point of care studies and maybe already authorized, they can add a screening claim upon request by agreeing to do this serial testing program and doing the post market study.

Now the existing templates for one time use OTC and asymptomatic screening, still are in existence. So if developers want to still use that pathway and get a one time use claim that's fine as well. But for the lower sensitivity, without data in the asymptomatic population we want that serial testing as part of the authorization and we want to confirm performance in a post market study. Hopefully I addressed all of your questions. There were a few there.

(Jeff Andrews): Thank you. If I was going to ask anything else, are you going to release a template for the post market study requirements in terms of sample size, number of positives, low positive?

Dr. Timothy Stenzel: So I think that's something that you can propose in a pre-EUA when you're requesting or an EUA when you're requesting this and we can confer with you. We expect that as the current template tests for 20 positives by a comparator, high sensitivity molecular comparator method, that that is still the expectation in the post market study. So 20 positives should - asymptomatic positives should do it.

(Jeff Andrews): Thank you.

Coordinator: Next question is from (Paul Bartow). Your line is open.

(Paul Bartow): Yes. Good afternoon. How are you doing, Tim? A quick question for you. So if we are contemplating being a lab and we are running an EUA authorized serology test and let's say it's authorized on venipuncture blood, if we want to do testing using a dried blood spot does that require a full validation or is that just simply a comparison study with the existing sample method?

Dr. Timothy Stenzel: So let me just make sure I understand the question. So you have a serology test and you want to have a sample type within your healthcare network, comes to your lab of a dried blood spot. Is this for a home collection or a healthcare collection?

(Paul Bartow): I'd be interested in the answer on either one, but I was contemplating an at home collection.

Dr. Timothy Stenzel: Yes. So for at home collection that is not considered an LDT situation but a device situation. And we have posted a template already with recommendations for validating a home dried blood spot collection. So I'd refer you to that on our FDA Web site.

If you are validating that as an additional sample type for - in your lab for a kit that you're using that's authorized, you can do that within the confines of your healthcare system in healthcare environments and it doesn't require an EUA submission. However, it would no longer be an EUA, considered an EUA authorized test.

(Paul Bartow): Got it. That's helpful. Okay. Thank you.

Coordinator: Next question is from (Susan Sharp). Your line is open.

(Susan Sharp): Thank you, Toby. Thank you, Tim. Quick question - if you collect a 10 swab pool with a single swab from each person but you place it in the same transport tube for media, with the assumption that you will re-collect the specimens from each one of those 10 people for individualized testing if that pool is positive, is that initial pool testing considered screening or surveillance?

Dr. Timothy Stenzel: That is a - can you state your name again? I didn't quite catch it.

(Susan Sharp): (Susan Sharp).

Dr. Timothy Stenzel: Oh. Hey, (Susan).

(Susan Sharp): Hey.

Dr. Timothy Stenzel: Yes. I mean that is an on the edge question between surveillance and screening and I'd recommend that you come in with a question into the Template email address with that question. Typically, when I've talked to people who are doing diagnostic or screening, looking at screening, they will

collect two swabs at the time of collection and will retain the second swab in order to deconvolute that.

Typically, diagnostic or screening testing provides results directly to an individual. If something's done purely for surveillance purposes following all the FAQs and guidances that are provided by the FDA and CMS and CDC, then that sort of combined pool could be used in that kind of program. So it depends. It depends on the details; it depends on following those various FAQs and guidances on how to do screening testing or diagnostic testing and/or surveillance testing.

Do, you know, whether you do purely surveillance or not - well, if you do purely surveillance do also look at our template on how to validate this type of swab pooling because it has different considerations than pooling media. In particular, with pooling media you're more concerned about losing sensitivity (dissolution).

When you're pooling swabs the concern has to do with do you concentrate any inhibition in that swab pooling, or do you push the overall viral load in that sample of a threshold that is no longer detectable by that particular assay? So we've definitely seen - we've projected it could be seen and then we've now definitely seen that if you load up a pool maybe, you know, with swabs, with a too high a viral load that you can get a false negative on that pool and that would be unfortunate.

So I'm sorry I can't be a little bit more definitive but it does depend. I'm happy to converse through the templates email box.

(Susan Sharp): Okay. Thank you. I did send in the question to the templates email and the question again, wasn't specifically answered. So I will try one more time. Thank you.

Dr. Timothy Stenzel: We'll also try to - just send it again. We'll alert the team to forward it to Toby. Actually, you can just ask them to forward it to Toby and Tim. Okay?

(Susan Sharp): Thank you.

Toby Lowe: Yes. And I think we can also, you know, clarify and this is also in the FAQs, that, you know, it does depend on what action you're taking. If the intent is to, you know, use this to identify individuals that can or cannot take some action, you know, whether it's return to school or return to work, or whatever it is, that would generally fall under screening, not surveillance. But we're happy to discuss further for your particular situation as well.

(Susan Sharp): Thank you.

Coordinator: Next question is from (Kay Taylor). Your line is open.

(Kay Taylor): Yes. Hi Tim. I wanted to follow up on the earlier question from (Jeff Andrews). So using this template, I understand that if we already have an authorized symptomatic antigen test with performance of greater than 80%, we would submit a signed amendment to our existing EUA to request a serial screening claim.

And then we would propose in that intended use, whether that is, you know, twice a week or three times. We would propose our intended use. And then with that negotiation FDA would authorize and we would then be obligated to do the post market authorization study.

Would that study be - in asymptomatic, but would that then if let's say we have twice a week serial testing screening claim, that post market study would be done according to that so you'd want to see, you know, whatever you're trying to claim in the intended use, whether it's two or three times a week, you'd want to see that design in the post market study. Did I understand that correctly?

Dr. Timothy Stenzel: That's absolutely correct. When it comes to OTC use we're anticipating that most developers will choose to send instead of a single test, but two tests per package, using this pathway. And they would instruct the user to test on day one and day two or day one and day three, day one and day four or something like that.

And we would be looking for confirmation of whatever specific scheme you would call for, for your serial testing, is validated and shows adequate performance.

(Kay Taylor): And this would be true whether your point of care going - a point of care device or an OTC device going for this. Correct?

Dr. Timothy Stenzel: Correct.

(Kay Taylor): That wouldn't change. Okay. Thank you very much. That helps, Tim.

Dr. Timothy Stenzel: Okay.

Coordinator: Next question is from (Kodumba Venkamp). Your line is now open.

Frequently Asked Questions Related to Compliance with the Applicable Preliminary Nationwide Injunction on Implementation and Enforcement of the Vaccination Requirement Pursuant to Executive Order 14043

Guidance to agencies originally issued January 24, 2022 and updated August 17, 2022

To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order (E.O.) 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Safer Federal Workforce Task Force guidance on other Federal agency safety protocols remains in effect.

Below are answers to frequently asked questions as guidance for agencies related to compliance with the nationwide injunction.

Maintenance and Use of Vaccination Information and Documentation

Q: Can agencies continue to require, request, and collect submission of vaccination information and documentation (including proof of primary series vaccination, additional doses, and booster shots) from employees and potential employees who have received an offer of employment, and maintain, review, and use that information and documentation?

A: As soon as possible and no later than Monday, August 22, 2022, to be consistent with Task Force guidance, agencies should pause requiring or requesting employees and potential employees to provide information about their COVID-19 vaccination status regardless of COVID-19 Community Levels, where COVID-19 safety protocols do not vary based on vaccination status.

Consistent with CDC guidance, for most Federal workplaces, COVID-19 workplace safety protocols will not vary based on vaccination status or otherwise depend on vaccination information. Where this is the case, agencies should no longer request or collect vaccination status information.

Agencies with employee COVID-19 vaccination requirements unrelated to E.O. 14043 and pursuant to other authorities can continue to require documentation of proof of vaccination from employees and potential employees subject to those requirements, as can agencies with other setting-specific dependencies on collecting vaccination information from employees in those settings. Agencies in these positions should consult with the Task Force, the agency's General Counsel, and the agency's Senior Agency Official for Privacy.

When agencies pause requiring, requesting, and collecting vaccination status information, such agencies must continue to preserve their vaccination information collection systems and the information collected to date from employees in accordance with National Archives and Records Administration records schedules; COVID-19 workplace safety may change in the future, or collection of this information from Federal employees may otherwise need to resume.

Job Posting Announcements and Hiring Actions

Q: Should agencies modify existing job postings that note there is a vaccination requirement for Federal employment pursuant to E.O. 14043?

A: Agencies should conspicuously note on Federal websites where they post job opportunity announcements that the vaccination requirement for Federal employees pursuant to E.O. 14043 is currently not being implemented and enforced. Agencies can use the following as a template for banners or similar posts on such Federal websites with job opportunity announcements:

> "To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees. Therefore, to the extent a Federal job announcement includes the requirement that applicants must be fully vaccinated against COVID-19 pursuant to Executive Order 14043, that requirement does not currently apply."

If an agency is not able to conspicuously post such a general notice where job opportunity announcements are posted, the agency should instead modify the existing individual job opportunity announcements to remove reference to vaccination requirements pursuant to E.O. 14043 or add a notice consistent with the template notice above.

Agencies should not add reference to a vaccination requirement pursuant to E.O. 14043 in new job opportunity announcements while the nationwide injunction is in place.

Q: Should agencies that have issued tentative and final offers of employment that reference the vaccination requirement pursuant to E.O. 14043 re-issue revised letters?

A: Yes, agencies should reissue tentative and final offers of employment to modify the reference to the COVID-19 vaccination requirement pursuant to E.O. 14043. Agencies can use the following as a template for language in such letters:

> "To ensure compliance with an applicable preliminary nationwide injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order 14043 on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees."

Exception Requests

Q: Can agencies process requests for disability or religious exceptions to the COVID-19 vaccination requirement pursuant to E.O. 14043 while the applicable preliminary nationwide injunction is in place?

A: No, agencies should not process requests they have already received for disability or religious exceptions to the COVID-19 vaccination requirement pursuant to E.O. 14043. They also should not ask

employees for additional information that may be required to process previously submitted exception requests, nor take any other steps related to adjudication of exception requests.

Agencies also should notify employees with pending exception requests that implementation or enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 is currently enjoined and that an exception therefore is not necessary so long as the nationwide injunction is in place.
If an agency receives a request for an exception from the COVID-19 vaccination requirement pursuant to E.O. 14043, the agency should accept the request, hold it in abeyance, and notify the employee who submitted the request that implementation or enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 is currently enjoined and that an exception therefore is not necessary so long as the nationwide injunction is in place.

Q: Can agencies renew, revise, or extend Paperwork Reduction Act clearance of their E.O. 14043 exception request forms while the applicable preliminary nationwide injunction is in effect?

A: No. The injunction prevents agencies from taking any action to implement or enforce the COVID-19 vaccination requirement pursuant to E.O. 14043, including actions to process requests for disability or religious exceptions. Accordingly, agencies should not seek, and OMB will not approve, renewals, revisions, or extensions for a clearance under the Paperwork Reduction Act (PRA) of E.O. 14043 exception request forms while the applicable preliminary nationwide injunction is in effect.

If an agency's PRA clearance for an E.O. 14043 exception request form expires during the applicable preliminary nationwide injunction, agencies should no longer have employees who want to submit an exception request fill out the expired form. However, as previously advised, agencies should continue to accept any request for an exception (even if informally made) and hold it in abeyance during the pendency of the injunction. If the injunction is lifted, agencies may then seek renewed clearance of their exception request form and, upon receiving such clearance, ask employees with pending exception requests to provide any further information that is needed.

<u>Enforcement Actions</u>

Q: Can agencies undertake preparatory work associated with enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 while the applicable preliminary nationwide injunction is in place?

A: No, agencies should not undertake preparatory work, such as drafting enforcement templates concerning disciplinary or adverse actions, associated with enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043.

Q: What should agencies do regarding disciplinary actions already in progress associated with enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 while the applicable preliminary nationwide injunction is in place?

A: Agencies should hold in abeyance all disciplinary actions related to enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043. This includes temporarily halting active suspensions as of January 21, 2022, and holding proposals to suspend or terminate non-compliant employees in abeyance.

Agencies should inform all employees who are subject to proposed or active disciplinary action that the implementation or enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 is currently enjoined and that the disciplinary action is being held in abeyance so long as the nationwide injunction is in place.

Q: Can agencies take disciplinary action to enforce other COVID-19 workplace safety protocols?

A: Agencies should continue processing disciplinary actions for other performance or compliance issues unrelated to enforcement of the vaccination requirement pursuant to E.O. 14043. This includes, for example, taking disciplinary actions associated with failure to comply with other COVID-19 workplace safety protocols.

Q: Do disciplinary actions associated with enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 that were already completed prior to the nationwide injunction need to be repealed, revoked, or rescinded?

A: No, at this time agencies do not need to revoke or rescind disciplinary actions associated with enforcement of the COVID-19 vaccination requirement pursuant to E.O. 14043 that were already effectuated prior to the nationwide injunction. For example, agencies do not need to repeal, rescind, or revoke letters of education and counseling, letters of reprimand, or proposals of suspensions, which may be stored in employee Official Personnel Folders or other agency files. In addition, agencies do not need to reinstate employees who have been terminated because of non-compliance with the COVID-19 vaccination requirement pursuant to E.O. 14043. Agencies should temporarily halt any active suspensions as of January 21, 2022, and should restore those employees to pay status.

Agencies should not use prior disciplinary actions taken pursuant to E.O. 14043 as predicates for further discipline.

<u>Other Vaccination Requirements</u>

Q: Can agencies with COVID-19 vaccination requirements unrelated to E.O. 14043 and pursuant to other authorities continue to implement and enforce those requirements?

A: Yes, agencies with COVID-19 vaccination requirements unrelated to E.O. 14043 and pursuant to other authorities can continue to implement and enforce those requirements. This includes proceeding with receiving, reviewing, and processing requests for exception to those requirements and enforcing the requirements through disciplinary actions consistent with agency policies.

Safer Federal Workforce Task Force
Model Agency COVID-19 Safety Principles
Last Updated September 15, 2022[1]

UPDATES IN THIS VERSION

- To ensure compliance with an applicable nationwide preliminary injunction, which may be supplemented, modified, or vacated, depending on the course of ongoing litigation, the Federal Government will take no action to implement or enforce the COVID-19 vaccination requirement pursuant to Executive Order (E.O.) 14043 on *Requiring Coronavirus Disease 2019 Vaccination for Federal Employees*. Guidance has been provided to agencies on complying with the applicable nationwide injunction. Any aspects of these Model Agency COVID-19 Safety Principles related to the vaccination requirement pursuant to E.O. 14043 are not in effect and will not be implemented or enforced by agencies while the injunction is in place. Safer Federal Workforce Task Force (Task Force) guidance on other Federal agency safety protocols remains in effect, including the protocols described in this document.
- Consistent with CDC guidance, for most Federal workplaces, COVID-19 workplace safety protocols will not vary based on vaccination status or otherwise depend on vaccination information. Where this is the case, agencies should pause requiring, requesting, or collecting vaccination status information from employees, contractor employees, and visitors.
- The Centers for Disease Control and Prevention (CDC) has set recommendations related to COVID-19 Community Levels, which measure the impact of COVID-19 illness on health and healthcare systems. Task Force guidance relies on CDC COVID-19 Community Levels county-level data to determine the appropriate prevention strategies to utilize at a given time, including with respect to requiring mask-wearing, encouraging consideration of physical distancing, avoiding crowding, and implementing screening testing for high-risk settings. In addition to guidance for agencies on monitoring COVID-19 Community Levels on a weekly basis, a chart providing an overview of Federal facility safety protocols by COVID-19 Community Level is below.
- Protocols have been updated consistent with CDC guidance for mask-wearing, physical distancing, screening testing, travel, post-exposure precautions, and isolation.
- For agency-hosted meetings, events, and conferences, there are no Government-wide restrictions, and agencies do not need to first seek approval of agency heads, regardless of the expected number of in-person participants or local COVID-19 Community Levels, unless otherwise required to do so by agency policy.

PURPOSE

The health and safety of all Federal employees, onsite contractor employees, and individuals interacting with the Federal workforce is of paramount concern for the Administration.

Section 2(a) of E.O. 13991 directs executive departments and agencies (hereafter, "agency" and collectively, "agencies") to "immediately take action, as appropriate and consistent with applicable law, to require compliance with CDC guidelines with respect to wearing masks, maintaining physical distance, and other public health measures by: on-duty or on-site Federal employees; on-site Federal contractors;

[1] Previous updates to these model agency COVID-19 safety principles were issued on September 13, 2021 and July 29, 2021. The original version of model agency COVID-19 safety principles was issued as an attachment to Office of Management and Budget memorandum M-21-15 on "COVID-19 Safe Federal Workplace: Agency Model Safety Principles" issued on January 24, 2021.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Delegation of Authority

Notice is hereby given that, under the authority vested in me by the Secretary, Department of Health and Human Services, I have redelegated to the Commissioner, Administration on Children, Youth and Families, with the authority to further redelegate to the Director, Family Youth Services Bureau, the authority to approve/disapprove cooperative research or demonstration projects under Section 1110 of the Social Security Act, and as amended hereafter, when such projects pertain to the abstinence education activities referenced in Public Law 108–447 at Title II, Division F.

This delegation excludes the authority to submit reports to Congress. Further, this delegation shall be exercised under the Department's existing delegation and policy on regulations and under financial and administrative requirements applicable to all Administration for Children and Families authorities. In addition, where all or part of any research or demonstration project is wholly financed with Federal funds made available under section 1110 of the Social Security Act, without any State, local, or other non-Federal financial participation, that project must be approved by the Secretary of Health and Human Services.

I have ratified any actions taken by the Commissioner, Administration on Children, Youth and Families, or any other Administration on Children, Youth and Families officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation. This delegation was effective on the date of signature.

Dated: January 21, 2005.

Wade F. Horn,

Assistant Secretary for Children and Families.

[FR Doc. 05–1896 Filed 2–1–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0040]

Authorization of Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax by Individuals at Heightened Risk of Exposure Due to Attack With Anthrax; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for Anthrax Vaccine Adsorbed (AVA) for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by the Department of Defense (DoD) to be at heightened risk of exposure due to attack with anthrax. FDA is issuing this Authorization under the Federal Food, Drug, and Cosmetic Act (the act), as requested by DoD. The Authorization contains, among other things, conditions on the emergency use of AVA. The Authorization follows the determination by DoD that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax. On the basis of such determination, Secretary of Health and Human Services Tommy G. Thompson (the Secretary) declared an emergency justifying the authorization of the emergency use of AVA. The Authorization, which includes an explanation of the reasons for its issuance, is reprinted in this Notice.

DATES: The Authorization is effective as of January 27, 2005.

ADDRESSES: Submit written requests for single copies of the Emergency Use Authorization to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Margaret O'K. Glavin, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the act (21 U.S.C. 360bbb–3), as amended by the Project BioShield Act of 2004 (Public Law 108–276), allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving a heightened risk of attack on the public or U.S. military forces. With this EUA authority, FDA can help assure that medical countermeasures may be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by such agents, when there are no adequate, approved, and available alternatives to protect the American people and the U.S. military.

Section 564(b)(1) of the act provides that, before an EUA may be issued, the Secretary must declare an emergency based on one of the following grounds:

(1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents;

(2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological, or nuclear agent or agents; or

(3) a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act (PHS Act) that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents.

Once the Secretary has declared an emergency justifying an authorization under section 564 of the act, FDA may authorize the emergency use of a drug, device, or biological product if the agency concludes, based on the information and data available to the agency, that the statutory criteria of section 564(c) of the act are satisfied. Under section 564(h)(1) of the act FDA is required to publish in the **Federal Register** notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. The explanation may include a summary of data submitted to FDA in an application

under section 505(i) or 520(g) of the act (21 U.S.C. 355(i) or 21 U.S.C. 360j(g)).

Section 564 of the act permits FDA to authorize, during the effective period of the declaration, the introduction into interstate commerce of a drug, device, or biological product intended for use in an actual or potential emergency. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), and 515 of the act (21 U.S.C. 355, 21 U.S.C. 360(k), 21 U.S.C. 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the circumstances of the emergency), FDA concludes:

(1) That the agent specified in the declaration of emergency can cause a serious or life-threatening disease or condition;

(2) That, based on the totality of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing—(a) the serious or life-threatening disease or condition referred to in paragraph (1); or (b) a serious or life-threatening disease or condition caused by a product authorized under section 564, or approved, cleared, or licensed under the act or PHS Act, for diagnosing, treating, or preventing the disease or condition referred to in paragraph (1) and caused by the agent specified in the declaration of emergency;

(3) That the known and potential benefits of the product outweigh the known and potential risks of the product when used to diagnose, prevent, or treat the serious or life-threatening disease or condition that is the subject of the declaration; and

(4) That there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such serious or life-threatening disease or condition.

II. EUA Request for AVA

On December 10, 2004, pursuant to section 564(b)(1)(B) of the act (21 U.S.C. 360bbb–3(b)(1)(B)), the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. On January 14, 2005, pursuant to section 564(b) of the act, and on the basis of such determination, Secretary of Health and Human Services Tommy G. Thompson declared an emergency justifying the authorization of the emergency use of AVA. Notice of the determination of the Deputy Secretary of Defense and the declaration of the Secretary of Health and Human Services is published elsewhere in this issue of the **Federal Register**.

III. Significance of Notice

The issuance of this Authorization for the emergency use of AVA is the first time that the EUA authority is being used. FDA intends to explain clearly the reasons for each issuance, termination, or revocation of an EUA. The agency wishes to make its decision-making understandable to help ensure that members of the public, and particularly those individuals who may be eligible to receive a medical product authorized for emergency use, are informed about the basis of an EUA determination. The amount of information that will be provided regarding each authorization will depend on the circumstances of the emergency. We anticipate that in some circumstances, an EUA will be issued very quickly, and time may not permit the agency to prepare supplementary documents beyond the letter of authorization and the notice required by section 564(h)(1) of the act. Other circumstances may afford greater opportunity to produce materials in addition to those prepared and disseminated as a condition of authorization under section 564(e) of the act. Thus, the amount of additional information that we will provide will necessarily vary on a case-by-case basis. The agency will publish notice of each EUA and intends also to make the notice and certain supplementary information available on its website and in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, which is open to the public between 9 a.m. and 4 p.m., Monday through Friday.

Because the statute is self-executing, FDA does not require regulations or guidance to implement the EUA authority. However, we believe that it would be helpful for stakeholders and the public to have more information about the EUA authority, and the process that the agency is proposing to adopt for the consideration of EUA requests. Accordingly the agency is planning to issue draft guidance on this topic in the near future.

IV. Electronic Access

An electronic version of this notice and the full text of the Authorization are available on the Internet at *http://www.fda.gov/ohrms/dockets/default.htm*.

V. The Authorization

Having consulted with NIH and CDC, and having concluded that the criteria for issuance of this Authorization under section 564(c) of the act are met, FDA has authorized the emergency use of AVA for prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by DoD to be at heightened risk of exposure due to attack with anthrax. The Authorization follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the act:

William Winkenwerder, Jr., M.D.
Assistant Secretary of Defense for Health Affairs
The Pentagon
Washington, D.C. 20301–1200

Re: Request for Emergency Use Authorization for the Armed Forces Pending Re-determination on the Licensed Use of Anthrax Vaccine Adsorbed for Protection Against Inhalational Anthrax

Dear Dr. Winkenwerder:

This is in response to your letter of December 22, 2004, requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) regarding the use of Anthrax Vaccine Adsorbed (AVA) for the prevention of inhalational anthrax, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act).

On December 10, 2004, pursuant to section 564(b)(1)(B) of the Act, 21 U.S.C. § 360bbb–3(b)(1)(B), the Deputy Secretary of Defense determined that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax.[1] On January 14, 2005, pursuant to section 564(b) of the Act, and on the basis of such determination, Secretary of Health and Human Services, Tommy G. Thompson declared an emergency justifying the authorization of the emergency use of AVA. Having consulted with the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC), and having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of AVA for prevention of inhalation anthrax,[2] subject to the conditions established herein.[3]

[1] You state in your letter that the Deputy Secretary of Defense has assigned authority from the Secretary of Defense to make the statutory determination under section 564(b)(1)(B) of the Act.

[2] The Secretary of Health and Human Services has delegated his authority to issue an EUA under section 564 to the FDA Commissioner.

[3] The terms ''inhalation anthrax'' and ''inhalational anthrax'' are used interchangeably.

I. Background

AVA was first licensed by NIH in November 1970.[4] Upon the delegation of vaccine regulation to FDA in 1972, FDA undertook a comprehensive review of the safety, effectiveness, and labeling of all vaccines licensed prior to July 1, 1972.[5] Under this review, independent advisory panels evaluated the safety and effectiveness data of vaccines to assure that they met appropriate standards. The advisory panel that reviewed AVA concluded that it is safe, effective, and not misbranded, and FDA issued a proposal to adopt the panel's recommendation (the Bacterial Vaccines and Toxoids Efficacy Review).[6]

In March 2003, six plaintiffs, known as John and Jane Doe 1 through 6, filed suit in the United States District Court for the District of Columbia (the Court) seeking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense (DoD), and to declare AVA an investigational drug when used for protection against inhalation anthrax. On December 22, 2003, the Court issued a preliminary injunction barring inoculations under the AVIP in the absence of informed consent or a Presidential waiver of the informed consent requirement.

In the **Federal Register** of January 5, 2004,[7] FDA published a final rule and final order in response to the report and recommendations of the independent advisory panel that reviewed the safety and effectiveness data pertaining to AVA. Following FDA's issuance of the final rule and final order, the Court lifted the preliminary injunction on January 7, 2004, except as it applied to the six Doe plaintiffs.

On October 27, 2004, the Court issued a memorandum opinion vacating and remanding the January 2004 final rule and final order to FDA for reconsideration, following an appropriate notice and comment period. The Court also enjoined operation of the AVIP for inoculation using AVA to prevent inhalation anthrax. On December 29, 2004, FDA published a proposed rule and proposed order reopening the comment period on the Bacterial Vaccine and Toxoids Efficacy Review for 90 days.[8] As a result of the Court's order of October 27, 2004, the use of AVA by DoD for the prevention of inhalation anthrax under the AVIP is deemed an unapproved use of an approved product for purposes of section 564(a)(2) of the Act. But for the Court's order, FDA would not consider the use of AVA for inhalation anthrax to be an unapproved use.

[4] Biological products are licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

[5] *See* 21 C.F.R. § 601.25.

[6] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51002 (Dec. 13, 1985).

[7] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255 (Jan. 5, 2004).

[8] Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Proposed Rule and Proposed Order, 69 Fed. Reg. 78281 (Dec. 29, 2004).

II. Criteria for Issuance of Authorization

Having considered the December 10, 2004, determination by the Deputy Secretary of Defense that there is a significant potential for a military emergency involving a heightened risk to U.S. military forces of attack with anthrax, and the January 14, 2005, declaration of emergency by the Secretary of Health and Human Services, and after consultation with NIH and CDC, I have concluded that the use of AVA to prevent inhalation anthrax meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

(1) anthrax (*Bacillus anthracis*) can cause a serious or life-threatening disease or condition;

(2) based on the totality of scientific evidence available to FDA, AVA is effective in preventing inhalation anthrax; therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act; and that the known and potential benefits of AVA, when used to prevent inhalation anthrax, outweigh the known and potential risks of the product; and

(3) there is no adequate, approved, and available alternative to AVA for preventing inhalation anthrax.[9]

Specifically, I have concluded, pursuant to section 564(c)(1) of the Act, that anthrax (*Bacillus anthracis*) can cause inhalation anthrax, which is a serious or life-threatening disease or condition. The fatality rate for inhalation anthrax in the United States is estimated to be approximately 45 percent to 90 percent. From 1900 to October 2001, there were 18 identified cases of inhalation anthrax in the United States, the latest of which was reported in 1976, with an 89 percent (16/18) mortality rate. Most of these exposures occurred in industrial settings, i.e., textile mills. From October 4, 2001, to December 5, 2001, a total of 11 cases of inhalation anthrax linked to intentional dissemination of *Bacillus anthracis* spores were identified in the United States. Five of these cases were fatal. These fatalities occurred despite aggressive medical care, including antibiotics.

I have concluded that, based on the totality of scientific evidence available to FDA, including data from at least one well-controlled field study, AVA is effective in preventing inhalation anthrax; therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act. In addition, pursuant to section 564(c)(2)(B) of the Act, I have concluded that it is reasonable to believe that the known and potential benefits of AVA outweigh the known and potential risks of the product. The available scientific evidence that supports these conclusions includes the following:

- A well-controlled efficacy field study using an earlier version of a protective antigen-based anthrax vaccine was conducted in mill workers from 1955-1959. In a comparison of anthrax cases between the placebo and vaccine groups, including both inhalation and cutaneous cases in those who were completely vaccinated, the calculated vaccine efficacy level against all reported cases of anthrax combined was 92.5 percent (lower 95 percent CI = 65 percent). The efficacy analysis included all cases of anthrax disease regardless of the route of exposure or manifestation of disease.
- Epidemiological surveillance data on the occurrence of anthrax disease in at-risk industrial settings for the years 1962-1974 provides further supportive evidence of the effectiveness of AVA. In that time period, individuals received either AVA, or an earlier version of anthrax vaccine. Of the 24 anthrax cases that occurred in mill employees during that period, no cases occurred in those who had received the full vaccination series.
- The safety of AVA was evaluated in a 5-year (1967-1971) open-label safety study in which 15,907 doses of AVA were administered to approximately 7,000 textile employees, laboratory workers, and other at-risk individuals. Severe local reactions were reported in 0.15 percent of doses administered (24 reports). There were 150 reports (0.94 percent of doses administered) of moderate local reactions and 1,373 reports (8.63 percent of doses administered) of mild local reactions. In the same open label study, four cases of systemic reactions were reported during a 5-year reporting period (<0.06 percent of doses administered). These reactions, which were reported to have been transient, included fever, chills, nausea, and general body aches.
- Recently (1996-1999), an assessment of safety was conducted as part of a randomized clinical study conducted by the U.S. Army Medical Research Institute of Infectious Diseases. Four of the 28 volunteers reported seven acute adverse events within 30 minutes after the subcutaneous administration of AVA. These adverse events included erythema (3), headache (2), fever (1), and elevated temperature (1). Of these events, a single patient reported the simultaneous occurrence of headache, fever, and elevated temperature (100.7°F). The most common local reactions reported after the first dose in this study were tenderness (71 percent), erythema (43 percent), subcutaneous nodule (36 percent), induration (21 percent), warmth (11 percent), and local pruritus (7 percent). Local reactions were found to occur more often in women. No abscess or necrosis was observed at the injection site.

I have concluded, pursuant to section 564(c)(3) of the Act, that there is no adequate, approved, and available alternative to AVA for preventing inhalation anthrax. No other drugs are approved for the prevention (pre-exposure) of anthrax infection. Antibiotics are effective against the germinated form of *Bacillus anthracis*, but are not effective against the spore form of the organism. Although antibiotics are available to treat anthrax infection, their effectiveness is limited, in part due to delays from the time of exposure to the initiation of treatment. Delays in the treatment of exposed persons are possible, considering the potential scenarios of exposure, and the difficulties that exist in identifying anthrax as the etiology of illness.

[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4).

III. Scope of Authorization

Pursuant to section 564(d)(1) of the Act, this authorization is limited to the use of AVA for the prevention of inhalation anthrax for individuals between 18 and 65 years of age who are deemed by DoD to be at heightened risk of exposure due to attack with anthrax.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of AVA, when used to prevent inhalation anthrax, outweigh the known and potential risks of the product for the population described above.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that AVA is effective in preventing inhalation anthrax, and therefore, it is reasonable to believe that AVA may be effective in preventing inhalation anthrax pursuant to section 564(c)(2)(A) of the Act. FDA has reviewed the scientific information available, including the studies described in Section II above, and concludes that AVA, when used for preventing inhalation anthrax, meets the standards set forth in section 564(c) of the Act.

FDA understands that DoD recognizes that the current AVA license describes an immunization schedule consisting of six doses. Certain details of DoD's EUA request are not specifically addressed in the package insert, however. DoD notes that for some personnel, the vaccination schedule was unavoidably disrupted, and DoD intends for such personnel to resume vaccinations at the point in the dosing schedule where they left off, for individuals eligible under the EUA. While this practice is not addressed in the package insert, the practice is consistent with the general recommendations of the Advisory Committee on Immunization Practices. When it is impracticable to provide a dose on a specific date recommended by the schedule, DoD intends to provide the vaccine dose as soon as practicable thereafter. Based on the totality of the scientific evidence available to FDA, it is reasonable to believe that such administration of AVA may be effective in preventing inhalation anthrax. Furthermore, the known and potential benefits of AVA, when used to prevent inhalation anthrax in the manner described above, outweigh the known and potential risks of the product. DoD also acknowledges that during the course of the EUA, the risk status of individuals initially eligible for vaccination under the EUA may change (e.g., changes in deployment or other circumstances). In such cases, DoD must determine whether such individuals continue to be at heightened risk of exposure due to attack with anthrax, and therefore, whether they continue to be eligible for vaccination with AVA under this EUA.

The use of AVA under this EUA must be consistent with and not contrary to the conditions of authorization set forth below. Subject to the foregoing limitations and under the circumstances set forth in the Deputy Secretary of Defense's determination of military emergency, AVA may be administered for the prevention of inhalation anthrax to individuals determined by DoD to be at heightened risk of exposure due to attack with anthrax.

IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Conditions Designed to Ensure that Health Care Providers or Authorized Dispensers Administering the Product Are Informed. DoD will conduct an educational and information program under appropriate conditions designed to ensure that health care providers or authorized dispensers administering AVA under this authorization are informed:

(1) that FDA has authorized the emergency use of AVA for preventing inhalation anthrax;

(2) of the significant known and potential benefits and risks of the emergency use of AVA, and the extent to which such benefits and risks are unknown; and

(3) of the alternatives to AVA that are available, and of their benefits and risks.

With respect to condition (2), above, relating to provision of the significant known and potential benefits and risks of the emergency use of AVA, DoD will assure that the manufacturer's package insert is available to all health care providers or authorized dispensers who administer AVA. DoD will also provide to all such health care providers or authorized dispensers the same information provided to potential vaccine recipients described immediately below.

Conditions Designed to Ensure that Individuals to Whom the Product is Administered Are Informed. DoD will conduct an educational and information program under appropriate conditions designed to ensure that individuals to whom AVA is administered are informed:

(1) that FDA has authorized the emergency use of AVA for preventing inhalation anthrax;

(2) of the significant known and potential benefits and risks of the emergency use of AVA, and of the extent to which such benefits and risks are unknown; and

(3) of the option to accept or refuse administration of AVA; of the consequences, if any, of refusing administration of the product; and of the alternatives to AVA that are available, and of their benefits and risks.

With respect to condition (3), above, relating to the option to accept or refuse administration of AVA, the AVIP will be revised to give personnel the option to refuse vaccination. Individuals who refuse anthrax vaccination will not be punished. Refusal may not be grounds for any disciplinary action under the Uniform Code of Military Justice. Refusal may not be grounds for any adverse personnel action. Nor would either military or civilian personnel be considered non-deployable or processed for separation based on refusal of anthrax vaccination. There may be no penalty or loss of entitlement for refusing anthrax vaccination.

This information shall read in the trifold brochure provided to potential vaccine recipients as follows:

You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.

Other information, as outlined in your request, is not a condition of this EUA, but may be provided, including: That unvaccinated people are more vulnerable to lethal anthrax infection; morbidity or mortality due to anthrax could threaten the lives of others in the unit who depend on each other; and anthrax infections could jeopardize the success of the mission. Individuals subject to the vaccination program may be informed that their military and civilian leaders strongly recommend anthrax vaccination, but such individuals may not be forced to be vaccinated. In addition, the issue of mandatory vaccination will be reconsidered by DoD after FDA completes its administrative process, which DoD expects to occur later this year.[10]

As a condition of this authorization, DoD will provide to each potential AVA recipient, prior to vaccination, information that meets the requirements set forth above. FDA has reviewed DoD's trifold brochure, submitted on January 19, 2005, and concludes that this brochure meets such requirements. DoD will obtain FDA's prior approval of any revision to the trifold brochure.

Conditions for the Monitoring and Reporting of Adverse Events Associated with the Emergency Use of AVA. DoD will, as a condition of this authorization, actively encourage health care providers or authorized dispensers and vaccine recipients to report adverse events to the Vaccine Adverse Events Reporting System (VAERS). In addition, we understand that DoD will conduct systematic monitoring of the health of recipients of AVA, e.g., cohort studies using the Defense Medical Surveillance System databases of active-duty military personnel; such monitoring is not a condition of this authorization.

Conditions Concerning Recordkeeping and Reporting, Including Records Access by FDA. DoD will, as a condition of authorization, record in individual medical records, including electronic immunization tracking systems, the names of individual recipients of AVA and the dates of vaccination. DoD will provide FDA access to such records.

Advertising and Promotional Descriptive Printed Matter. FDA has the authority, under section 564(e)(4) of the Act to establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of AVA under this authorization. As a condition of this EUA, all advertising and promotional descriptive printed matter relating to the use of AVA shall be consistent with the trifold as well as the standards and requirements set forth in this authorization.

V. Duration of Authorization

This EUA will be effective for 6 months from the date of issuance. However, this EUA may be extended within the duration of the declaration of emergency if the criteria under section 564(c) of the Act for issuance of such

[10] *See* Section I of this authorization.

authorization are still met. Moreover, the EUA will cease to be effective when the declaration of emergency is terminated under section 564(b) of the Act or the EUA is revoked under section 564(g) of the Act.

Thank you in advance for your cooperation in implementing this EUA.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.

Dated: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2028 Filed 1–31–05; 11:39 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Mental Health Services; Notice of Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Center for Mental Health Services (CMHS) National Advisory Council in February 2005.

A portion of the meeting will be open and will include a roll call, general announcements, Director's and Administrator's Reports, as well as presentations and discussions about Mental Health System Transformation.

Attendance by the public will be limited to space available. Public comments are welcome. Please communicate with the individual listed below as contact to make arrangements to comment or to request special accommodations for persons with disabilities.

The meeting also will include the review, discussion, and evaluation of grant applications. Therefore a portion of the meeting will be closed to the public as determined by the Administrator, SAMHSA, in accordance with Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App. 2 Section 10(d).

Substantive program information, and a roster of Council members may be obtained by accessing the SAMHSA Advisory Committee website (*http://www.samhsa.gov*) or by communicating with the contact whose name and telephone number are listed below. A summary of the meeting and the transcript for the open session will also be available on the SAMHSA Advisory Committee Web site as soon as possible after the meeting.

Committee Name: Substance Abuse and Mental Health Services Administration, Center for Mental Health Services National Advisory Council.

Meeting Date: February 16–17, 2005.

Place: Sugarloaf Room, 1 Choke Cherry Road, Rockville, MD 20857.

Type: Open: February 16, 2005, 9 a.m.—5 p.m.; February 17, 2005, 9:30 a.m.—1 p.m.

Closed: February 17, 2005, 9 a.m.—9:30 a.m.

Contact: Diane Abbate, MA, Acting Executive Secretary, 1 Choke Cherry Road, Room 6–1075, Rockville, Maryland 20857. Telephone: (240) 276–1830, and FAX (240) 276–1850. E-mail: *dabbate@hhs.samhsa.gov.*

Dated: January 26, 2005.

Toian Vaughn,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 05–1923 Filed 2–1–05; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Notice of Intent To Request Renewal From the Office of Management and Budget (OMB) of One Current Public Collection of Information; Flight Crew Self-Defense Training—Registration and Evaluation

AGENCY: Transportation Security Administration (TSA), DHS.

ACTION: Notice.

SUMMARY: TSA invites public comment on an existing information collection requirement, abstracted below, that will be submitted to OMB for renewal in compliance with the Paperwork Reduction Act.

DATES: Send your comments by April 4, 2005.

ADDRESSES: Comments to be delivered to Katrina Wawer, Information Collection Specialist, TSA Headquarters, East Tower, Floor 7, TSA–9, 601 South 12th Street, Arlington, VA 22202–4220; facsimile (571) 227–2594; email *katrina.wawer@dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Katrina Wawer, Information Collection Specialist (571) 227–1995.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid OMB control number. Therefore, in preparation for submission of the specified information collection for renewal, TSA solicits comments in order to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology where appropriate.

1652–0028, Flight Crew Self-Defense Training—Registration and Evaluation. TSA is seeking to renew information collection request number 1652–0028 to continue compliance with statutory mandate. Section 603 of Vision 100—Century of Aviation Reauthorization Act, Public Law 108–176, requires TSA to develop and provide a voluntary advanced self-defense training program for flight and cabin crew members of air carriers providing scheduled passenger air transportation. TSA collects limited biographical information from flight crew members to confirm their eligibility for training. TSA also asks participants to complete an anonymous and voluntary evaluation form after the training is completed to assess the quality of the training. TSA requests this renewal to continue confirming participants' eligibility and attendance for the training program, as well as to continue to assess training quality. The estimated number of annual respondents is 3,000 and estimated annual burden is 750 hours. There is no estimated annual cost burden to respondents.

The approval of this information collection expires on April 30, 2005.

Issued in Arlington, Virginia, on January 25, 2005.

Lisa S. Dean,

Privacy Officer.

[FR Doc. 05–1926 Filed 2–1–05; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Notice of Intent To Request Renewal From the Office of Management and Budget (OMB) of a Current Public Collection of Information; Airport Security

AGENCY: Transportation Security Administration (TSA), Department of Homeland Security (DHS).

ACTION: Notice.

103D CONGRESS
2d Session

COMMITTEE PRINT

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IS MILITARY RESEARCH HAZARDOUS TO VETERANS' HEALTH? LESSONS SPANNING HALF A CENTURY

A STAFF REPORT PREPARED FOR THE

COMMITTEE ON VETERANS' AFFAIRS

UNITED STATES SENATE

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DECEMBER 8, 1994

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IS MILITARY RESEARCH HAZARDOUS TO VETERANS' HEALTH? LESSONS SPANNING HALF A CENTURY

I. INTRODUCTION

During the last 50 years, hundreds of thousands of military personnel have been involved in human experimentation and other intentional exposures conducted by the Department of Defense (DOD), often without a servicemember's knowledge or consent. In some cases, soldiers who consented to serve as human subjects found themselves participating in experiments quite different from those described at the time they volunteered. For example, thousands of World War II veterans who originally volunteered to "test summer clothing" in exchange for extra leave time, found themselves in gas chambers testing the effects of mustard gas and lewisite.[1] Additionally, soldiers were sometimes ordered by commanding officers to "volunteer" to participate in research or face dire consequences. For example, several Persian Gulf War veterans interviewed by Committee staff reported that they were ordered to take experimental vaccines during Operation Desert Shield or face prison.[2]

The *goals* of many of the military experiments and exposures were very appropriate. For example, some experiments were intended to provide important information about how to protect U.S. troops from nuclear, biological, and chemical weapons or other dangerous substances during wartime. In the Persian Gulf War, U.S. troops were intentionally exposed to an investigational vaccine that was intended to protect them against biological warfare, and they were given pyridostigmine bromide pills in an experimental protocol intended to protect them against chemical warfare.

However, some of the studies that have been conducted had more questionable motives. For example, the Department of Defense (DOD) conducted numerous "man-break" tests, exposing soldiers to chemical weapons in order to determine the exposure level that would cause a casualty, i.e., "break a man."[3] Similarly, hundreds of soldiers were subjected to hallucinogens in experimental programs conducted by the

[1]Veterans at Risk: The Health Effects of Mustard Gas and Lewisite, Pechura, C.M. & Rall, D.P. (Eds.) Institute of Medicine, National Academy Press, Washington, DC, 1993, p. 65.

[2]In a survey of 150 Persian Gulf War veterans conducted by Committee staff, 15 of 17 military personnel receiving botulinum toxoid in the Gulf war were told they could not refuse the vaccination; 54 of 73 military personnel receiving pyridostigmine were told they could not refuse the drug.

[3]Veterans at Risk, op. cit., p. 36.

DOD in participation with, or sponsored by, the CIA.[4,5] These servicemembers often unwittingly participated as human subjects in tests for drugs intended for mind-control or behavior modification, often without their knowledge or consent. Although the ultimate goal of those experiments was to provide information that would help U.S. military and intelligence efforts, most Americans would agree that the use of soldiers as unwitting guinea pigs in experiments that were designed to harm them, at least temporarily, is not ethical.

Whether the goals of these experiments and exposures were worthy or not, these experiences put hundred of thousands of U.S. servicemembers at risk, and may have caused lasting harm to many individuals.

Every year, thousands of experiments utilizing human subjects are still being conducted by, or on behalf of, the DOD. Many of these ongoing experiments have very appropriate goals, such as obtaining information for preventing, diagnosing, and treating various diseases and disabilities acquired during military service. Although military personnel are the logical choice as human subjects for such research, it is questionable whether the military hierarchy allows for individuals in subordinate positions of power to refuse to participate in military experiments. It is also questionable whether those who participated as human subjects in military research were given adequate information to fully understand the potential benefits and risks of the experiments. Moreover, the evidence suggests that they have not been adequately monitored for adverse health effects after the experimental protocols end.

Veterans who become ill or disabled due to military service are eligible to receive priority access to medical care at VA medical facilities and to receive monthly compensation checks. In order to qualify, they must demonstrate that their illness or disability was associated with their military service. Veterans who did not know that they were exposed to dangerous substances while they were in the military, therefore, would not apply for or receive the medical care or compensation that they are entitled to. Moreover, even if they know about the exposure, it would be difficult or impossible to prove if the military has not kept adequate records. It is therefore crucial that the VA learn as much as possible about the potential exposures, and that the DOD assume responsibility for providing such information to veterans and to the VA.

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[4]Testimony of Deanne Siemer, general counsel, Department of Defense, hearing before the Subcommittee on Health and Scientific Research, Committee on Human Resources, U.S. Senate, "Human Drug Testing by the CIA, 1977," September 20-21, 1977, pp. 157-168.

[5]Testimony of Sidney Gottlieb, M.D., former CIA agent, hearing before the Subcommittee on Health and Scientific Research, Committee on Human Resources, U.S. Senate, "Human Drug Testing by the CIA, 1977," September 20-21, 1977, pp. 169-217.

II. BACKGROUND

A. CODES, DECLARATIONS, AND LAWS GOVERNING HUMAN EXPERIMENTATION

The Nuremberg Code is a 10-point declaration governing human experimentation, developed by the Allies after World War II in response to inhumane experiments conducted by Nazi scientists and physicians. The Code states that voluntary and informed consent is absolutely essential from all human subjects who participate in research, whether during war or peace. The Code states:

> The person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health and person which may possibly come from his participation in the experiments.[6]

There is no provision in the Nuremberg Code that allows a country to waive informed consent for military personnel or veterans who serve as human subjects in experiments during wartime or in experiments that are conducted because of threat of war. However, the DOD has recently argued that wartime experimental requirements differ from peacetime requirements for informed consent. According to the Pentagon, "In all peacetime applications, we believe strongly in informed consent and its ethical foundations.....But military combat is different."[7] The DOD argued that informed consent should be waived for investigational drugs that could possibly save a soldier's life, avoid endangerment of the other personnel in his unit, and accomplish the combat mission.

More than a decade after the development of the Nuremberg Code, the World Medical Association prepared recommendations as a guide to doctors using human subjects in biomedical research. As a result, in 1964 the Eighteenth World Medical Assembly met in Helsinki, Finland, and adopted recommendations to be used as an ethical code by all medical doctors conducting biomedical research with human subjects. This code, referred to as the Declaration of Helsinki, was

[6]The Nuremberg Code, from Trials of War Criminals before the Nuremberg Military Tribunals, U.S. Government Printing Office, Washington, DC, 1948.

[7]55 Federal Register 52,814-52,817 (December 21, 1990), "Informed Consent for Human Drugs and Biologics: Determinations that Informed Consent is Not Feasible."

healthy individuals, since the dosage is small and the patients have received neuromuscular blocking agents.

The bromide that is included in pyridostigmine bromide pills is known to sometimes cause problems referred to as "bromide intoxication" when used for the treatment of myasthenia gravis.[53] Bromide intoxication may cause confusion, irritability, tremor, memory loss, psychotic behavior, ataxia, stupor, and coma. Some patients with bromide intoxication have a skin disorder of the face and hands resembling acne. A 60 mg tablet of the commercially available pyridostigmine bromide contains 18.4 mg bromide (30.6 percent).[54,55]

FDA has not approved pyridostigmine bromide for repeated use in healthy individuals as an antidote enhancer or for any other reason. Since it would be unethical to expose individuals to potentially lethal chemical weapons in order to evaluate the *efficacy* of pyridostigmine, this use has only been studied on animals. The product is therefore an investigational drug when used as an antidote enhancer for treating nerve gas poisoning.

Botulinum toxoid is an unapproved vaccine that is used to protect laboratory workers and others who are likely to be exposed to botulism. Botulism is caused by at least one of seven neurotoxins produced by the bacteria Clostridium botulinum. When home-canning of food was common, food poisoning was the most common cause of botulism in the United States; the bacteria in the food produces a toxin which is eaten. Today, the most common form of botulism occurs in infants, since the bacteria that produces the toxin can thrive in a baby's intestinal tract.

A botulism vaccine that is intended to protect against five of seven neurotoxins (called A,B,C,D,E) is produced by the Michigan Department of Health. This is called pentavalent toxoid. This vaccine is not a licensed product and must be distributed as an Investigational New Drug (IND).

Efficacy. Desert Shield began on August 8, 1990. Since the air war did not begin until January 16, 1991, and the ground war took place from February 24-27, 1991, the Pentagon had several months to review the possible use of investigational drugs and vaccines.

In December 1990, the FDA advised the Department of Defense that it would be unable to test the botulism vaccine for efficacy, presumably because of limited time before the onset of the war. The FDA agreed to test the vaccine for safety, but these tests were not completed until late January 1991. At a meeting of the Informed Consent Waiver Review Group (ICWRG) on December 31, 1990, a representative of FDA's Center for Biologics Evaluation and Research discussed the vaccine, explaining that the existing supply was nearly 20 years old and consisted of three lots, stored under continuous

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[53]Wacks, I., Oster, J.R., Perez, G.O., & Kett, D.H. "Spurious hyperchloremia and hyperbicarbonatemia in a patient receiving pyridostigmine bromide therapy for myasthenia gravis," *American Journal of Kidney Diseases*, Vol. XVI, No. 1, July 1990, pp. 76-79.

[54]Ibid.

[55]Mestinon is the brand name for one form of pyridostigmine bromide available in the United States.

refrigeration.[56] Given the age of these vaccines, there were concerns about their safety.

The recommended schedule for immunization with the pentavalent vaccine includes a series of three initial injections at 0, 2, and 12 weeks, followed by a booster 12 months after the first injection. According to the Centers for Disease Control's Center for Infectious Diseases, subjects given the vaccine did not have detectable antitoxin titers after the first two shots in the initial series, which means that they were unlikely to be protected at week 2.[57] If for any reason only two immunizations can be given, at least 4 to 8 weeks should elapse between injections if most individuals are to be protected against the disease.[58]

Safety. The Michigan Department of Health reported that 4.2 percent of patients reported a sore arm or other local reactions to the initial series of three shots, and 12.1 percent had local reactions to the booster shots.[59] Almost 3 percent had systemic reactions, such as general malaise, after either the initial three shots or the booster shots. Because of the relatively large percentage of adverse reactions, new lots of the vaccine were manufactured in 1971. However, there is no evidence that the newer lots produced fewer adverse reactions than the older lots.

In her review of the DOD's application for use of botulinum toxoid in the Persian Gulf, an FDA reviewer pointed out that in 1973, the Centers for Disease Control had considered terminating the distribution of the vaccine because of the relatively large number of individuals who had negative reactions to it.[60] The FDA reviewer also pointed out that "there are no efficacy data in humans" and that the dose for humans was an estimate based on results from guinea pigs. In addition, potency testing had suggested that the vaccine would not be effective against two of the five botulism toxins.

According to the Michigan Department of Health, the effects of the botulism vaccine on pregnant women had not been studied prior to its use in the Persian Gulf War.

Anthrax vaccine is an FDA-approved vaccine that is considered safe and effective for individuals whose skin may come in contact with animal products such as hides, hair, or bones likely to contain the anthrax infection. It is also recommended for veterinarians and

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[56]Minutes of meeting of the Informed Consent Waiver Review Group (ICWRG), Food and Drug Administration, December 31, 1990.

[57]Ellis, R.J. Immunobiologic agents and drugs available from the Centers for Disease Control: Descriptions, recommendations, adverse reactions, and serologic response. Third Edition. Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services, Atlanta, GA, March 1982.

[58]Middlebrook, J.L. "Contributions of the U.S. Army to Botulinum Toxin Research," Botulinum and Tetanus Neurotoxins, Das Gupta, B.R., (Ed.), Plenum Press, New York, 1993, pp. 515-519.

[59]Informational material for the use of pentavalent (ABCDE) botulinum toxoid aluminum phosphate adsorbed, Protocol #392, Centers for Disease Control, Public Health Service, U.S. Department of Health and Human Services, May 1992.

[60]Review by Ann Sutton to the IND record, November 14, 1990; in Committee files.

others who are likely to touch infected animals.[61] However, the vaccine's effectiveness against *inhaled* anthrax is unknown. Unfortunately, when anthrax is used as a biological weapon, it is likely to be aerosolized and thus inhaled. Therefore, the efficacy of the vaccine against biological warfare is unknown.

It appears that there is only one relevant animal study which showed that anthrax vaccine apparently provided additional protection against relapse in monkeys exposed to inhalation anthrax and treated with antibiotics.[62] Although the results of this study suggest the vaccine might protect against anthrax that has been sprayed, it is not sufficient to prove that anthrax vaccine is safe and effective as used in the Persian Gulf. The vaccine should therefore be considered investigational when used as a protection against biological warfare.

The anthrax vaccine is given as three injections 2 weeks apart, followed by three additional injections given 6, 12, and 18 months after the initial injection. If immunity is to be maintained, subsequent booster injections of anthrax vaccine are recommended at 1-year intervals.[63] According to the Interagency Task Force on Persian Gulf War Illnesses, one dose provides some immunity in 85 percent of those individuals vaccinated.[64]

According to the Michigan Department of Public Health which manufactures anthrax vaccine, it is not known whether anthrax vaccine is safe for pregnant women or their offspring.

III. FINDINGS AND CONCLUSIONS

A. FOR AT LEAST 50 YEARS, DOD HAS KNOWINGLY EXPOSED MILITARY PERSONNEL TO POTENTIALLY DANGEROUS SUBSTANCES, OFTEN IN SECRET.

The U.S. General Accounting Office issued a report on September 28, 1994, which stated that between 1940 and 1974, DOD and other national security agencies studied hundreds of thousands of human subjects in tests and experiments involving hazardous substances.[65] GAO stated that some tests and experiments were conducted in secret. Medical research involving the testing of nerve agents, nerve agent antidotes, psychochemicals, and irritants was often classified. Additionally, some work conducted for DOD by contractors still remains classified today. For example, the Central Intelligence Agency (CIA) has not released the names of 15 of the approximately 80 organizations that conducted experiments under the MKULTRA

[61]Informational material for the use of anthrax vaccine adsorbed, Michigan Department of Public Health, U.S. License No. 99, 1978.

[62]Friedlander, A.M., Welkos, S.L., Pitt, M.L.M., et al. "Postexposure prophylaxis against experimental inhalation anthrax," *Journal of Infectious Diseases*, Vol. 167, 1993, pp. 1239-1242.

[63]Anthrax vaccine adsorbed, package insert, Michigan Department of Public Health, Lansing, MI, 1978.

[64]"Summary of the issues impacting upon the health of Persian Gulf War veterans," Version 1.1, March 3, 1994.

[65]"Human Experimentation, An Overview on Cold War Era Programs," U.S. General Accounting Office, September 28, 1994, GAO/T-NSIAD-94-266.

maneuvers."[70] At the time of his discharge from the military, he could not even describe his exposures to a Navy doctor who was trying to determine the cause of his severe respiratory illnesses. Although Mr. Harrison has suffered from recurrent breathing problems and has greatly diminished pulmonary function, he has never received any compensation for his illness. According to the VA and DOD, his medical and services records have been lost, making it difficult to prove that his disability is service-connected.

Cold War Veterans

During the years immediately following World War II, military personnel were intentionally exposed to radiation during the testing of atomic bombs and during radioactive releases. While it is unclear how many of these servicemembers were intentionally exposed to what were known to be harmful levels of radiation, there is clear evidence that in some cases military personnel were ordered to locate themselves in areas of high radioactive fallout. They were given no choice in the matter, and they were not told of the potential risks of those exposures.

Similarly, military personnel were intentionally given hallucinogenic drugs to determine the effects of those drugs on humans. The servicemembers were not told that they would be given experimental drugs, they had no choice of whether or not to take them, and even after the unusual effects of the drugs were obvious to researchers, the unwitting human subjects were given no information about the known effects of the drugs. Even if the DOD did not know about the potential long-term effects of the drugs, that would not justify their failure to provide information to thousands of servicemembers about the known short-term effects of the drugs.

Persian Gulf War Veterans

Persian Gulf veterans were also given investigational vaccines and ordered not to tell anyone. In a Committee survey of 150 individuals who served in the military during the Persian Gulf War (see Appendix), many of those surveyed indicated they were ordered, under threat of Article 15 or court martial, to discuss their vaccinations with no one, not even with medical professionals needing the information to treat adverse reactions from the vaccine. Similarly, 86 percent of the military personnel who told the Committee that they were ordered to take pyridostigmine bromide reported that they received no information on what they were taking or the drug's potential risks. According to a DOD study published in the Journal of the American Medical Association, commanding officers and medical personnel were also inadequately informed about the investigational drugs; as a result, they were ill-prepared to recognize or treat military personnel who experienced side effects.[71]

[70]Hearing, May 6, 1994; John T. Harrison, written statement submitted for the record.

[71]Although the study was published in the *Journal of the American Medical Association*, these results were not reported in the published article. They are reported in an unpublished report, Survey #1, Food and Drug Administration IND 23,509, Operation Desert Storm/Shield, May 27, 1992.

B. DOD HAS REPEATEDLY FAILED TO COMPLY WITH REQUIRED ETHICAL STANDARDS WHEN USING HUMAN SUBJECTS IN MILITARY RESEARCH DURING WAR OR THREAT OF WAR.

The major principle of all research ethics involving human subjects, as described by the Nuremberg Code, the Declaration of Helsinki, and the "Common Rule" of the U.S. Government, states that the voluntary, competent, informed, and understanding consent of the subject is absolutely essential, whether during war or peace.[72]

These standards are more than 50 years old. For example, the Nuremberg Code was based on testimony of two U.S. physicians, Drs. Leo Alexander and Andrew Ivy, who served as expert medical witnesses for the Nazi crime prosecutors. The code was not the outcome of an attempt to frame a new code of ethics, but rather a description of criteria said to be widely accepted by the medical profession at the time.[73] Therefore, DOD research during the 1940's was clearly conducted in an era when researchers were well aware of ethical codes regarding the use of human subjects.

The Department of Defense has violated these well-established ethical principles each time soldiers are required to participate in military research or take investigational drugs or vaccines or are not adequately informed about the risks of the experiments.

World War II Veterans

Many individuals were recruited for various military experiments of mustard gas and lewisite under the guise of testing clothing, without being warned beforehand that they would be exposed to dangerous chemicals. Additionally, young servicemembers frequently reported that they were enticed to volunteer for experiments by being promised extra leave time from duty.

For example, in 1944, Nathan Schnurman was a 17-year-old sailor who was recruited to test Navy summer clothing, in exchange for a 3-day pass. Instead, he participated in the testing of gas masks and clothing while he was locked in a gas chamber and exposed to mustard gas and lewisite. Mr. Schnurman believes that he was not really a volunteer since the research was misrepresented. Additionally, Mr. Schnurman stated in written testimony submitted to the Committee that "many were denied the 3-day pass, and many went to their graves without revealing this story."[74] Perhaps most outrageous, Mr. Schnurman was not allowed to leave the gas chamber when he became violently ill. Mr. Schnurman testified before the Committee on the Judiciary of the U.S. House of Representatives that, "During my sixth exposure in the chamber, I determined something was wrong. I called to the corpsman, via an intercom, and informed him of my condition, and what was happening and requested I be released from the chamber, now. The reply, was `No' as they had not completed the experiment. I became very nauseous. Again, I requested to be released from the chamber. Again,

[72]The Nuremberg Code, op. cit.

[73]"Annas, G.J. & Grodin, M.A. "The Nazi Doctors and the Nuremberg Code," Human Rights in Human Experimentation, Oxford University Press, 1992, p 152.

[74]Hearing, May 6, 1994; Nathan J. Schnurman, written statement submitted for the record.

permission was denied. Within seconds after the denial, I passed out in the chamber. What happened after that, I don't know. I may only assume, when I was removed from the chamber, it was presumed I was already dead."[75]

John William Allen enlisted in the U.S. Navy in 1945 at the age of 17. Immediately after boot camp, he volunteered to test summer uniforms so he could go home before shipping out. His test clothing consisted of one pair of pants, undershorts, a gas mask, and a shirt that had been used in previous experiments and was therefore impregnated with toxic chemicals. According to Mr. Allen, the actual testing consisted of determining the amount of sulfur mustard that would cause illness ("man-break" test), not the testing of summer uniforms. He was exposed several times to sulfur mustard and was removed from further exposure on May 5, 1945, when he passed out in the gas chamber. A physical examination on May 14, 1945, revealed many wounds as the result of exposure to mustard gas.

Mr. Allen stated in written testimony submitted to the Committee, "The government has lied to us for 50 years over and over again. If I would have been shot on the front lines at least I would had it on my record and would have received medical treatment."[76]

Persian Gulf War Veterans

Almost 50 years after World War II veterans were exposed to unethical research, the Department of Defense again failed to comply with the well-established ethical requirement that all soldiers and civilians make an informed choice of whether or not to use investigational medical treatment.

1. *Military personnel were not given the opportunity to refuse investigational drugs.*

When the Department of Defense began preparations for Desert Shield and Desert Storm in 1990, officials were extremely concerned about the need to protect U.S. troops against chemical and biological weapons that were believed to have been developed by Iraq. However, the DOD lacked drugs and vaccines that were proven safe and effective to safeguard against expected weapons, such as soman and botulism.

Under the Food, Drug, and Cosmetics Act, all vaccines and medical products must be proven safe and effective by the Food and Drug Administration (FDA) in order to be sold and distributed in the United States, or used by U.S. troops. However, DOD officials were interested in using a botulinum toxoid, which is a vaccine to prevent botulism, that was *not* approved by FDA. They also wanted to use pyridostigmine bromide, a medication to protect U.S. troops against chemical nerve agents. Although approved by the FDA for treating patients with a neurological disorder called myasthenia gravis,

[75]Testimony of Nathan Schnurman, WWII veteran, mustard gas test subject, hearing before the Subcommittee on Administrative Law and Governmental Relations, Committee on the Judiciary, U.S. House of Representatives, "Government-Sponsored Tests on Humans and Possible Compensation for People Harmed in the Tests," February 2, 1994.

[76]Hearing, May 6, 1994; John William Allen, written statement submitted for the record.

pyridostigmine is not proven safe or effective for repeated use by *healthy* persons under any circumstances, and is normally unavailable in doses that would be likely to be safe for healthy individuals.[77]

Under current law, the unapproved vaccine and the investigational use of pyridostigmine for healthy individuals could only be administered under an Investigational New Drug (IND) procedure.[78] Under an IND, any individual who is given the investigational product must give informed consent, i.e., must be told of the potential risks and benefits of the product, orally and in writing, and choose freely whether or not to participate. In addition, the IND requires that the medical product be distributed under carefully controlled conditions where safety and effectiveness can be evaluated.

In August 1990, the DOD contacted FDA to review regulatory restrictions of DOD's plan to use pyridostigmine and botulinum toxoid for U.S. troops in the Persian Gulf. The major focus of the meeting was informed consent. The DOD sought a waiver of requirements for informed consent for the use of pyridostigmine bromide and botulinum toxoid, arguing that these investigational products had well-established uses and were safe. They also claimed that there were no reasonable alternatives. According to minutes of the meeting, "FDA expressed some concern about liability and the need to comply with the regulations," and FDA's Deputy Director for Drug Review "pointed out the need to establish an appropriate investigational framework to collect observational data and evaluate the military medical products in question."[79]

In summary, DOD informed FDA that they did not want to abide by informed consent regulations, and FDA officials pointed out that pyridostigmine and botulinum toxoid were investigational and that there are laws regulating how they can be used. DOD claimed that "under the DOD directive the Secretary of Military Departments [could] dictate the use of unapproved FDA regulated products" in the Persian Gulf, but "DOD's current position is that this not their primary choice at this time."[80]

The issue was debated by the two agencies for several months. Finally, at a meeting on December 31, 1990, an agreement was reached. According to minutes of that meeting, DOD officials agreed that the botulism vaccine would be administered by trained individuals with a health care background, and that information would be provided orally "at minimum, and in written form if feasible, to all personnel receiving the vaccine."[81] Officials from the DOD said that the feasibility of distributing an information sheet would depend on many factors, and would vary from location to

[77]Pyridostigmine is approved by the FDA at a one-time dosage of 15 mg to reverse the effects of certain drugs given during anesthesia.

[78]55 Federal Register 52,814-52,817 (December 21, 1990).

[79]Memorandum for Record, August 30, 1990, submitted by Craig R. Lehmann, Lt. Col., USAF, BSC; in Committee files.

[80]FDA memorandum from Richard Klein and Ann Graham to Stuart Nightingale, September 7, 1990; in Committee files.

[81]Draft of minutes, meeting between officials of DOD and FDA, December 31, 1990, provided by FDA to Committee; in Committee files.

location within the military theater of operation. DOD officials "reiterated that at least verbal [sic] information would be provided to each person receiving the vaccine."

The FDA Informed Consent Waiver Review Group recommended that pregnant women be excluded from receiving the vaccine and that information about the vaccine be "posted at places where vaccine is administered." However, DOD argued that pregnant women would be at greater risk from exposure to botulism toxins than to the vaccine, and FDA agreed that instead of excluding pregnant women, a statement would be added to the information sheet stating that, "If you are pregnant, it is not known if this vaccine will hurt the unborn baby, however, most vaccines do not."[82]

In their application for a waiver, DOD described the safeguards that would be in place regarding the distribution of the botulism vaccine. In addition to oral warnings regarding the vaccine, DOD promised that the soldiers would be observed for 30 minutes after receiving the vaccine, and if possible, they would also be checked again 48 hours later. In addition, DOD claimed that they would provide all three vaccine injections and stated that all three were necessary to provide protection.

FDA granted the waiver on a temporary basis, concurring that obtaining informed consent during wartime is not feasible in a specific military operation involving combat or the threat of combat.[83] On January 8, 1991, Dr. David Kessler, FDA Commissioner, wrote to the Assistant Secretary of Defense for Health Affairs regarding the waiver for informed consent for pyridostigmine. In his letter, Dr. Kessler agreed that since there was "no available satisfactory alternative therapy" for protection against organophosphorus nerve gas, he would "concur with your assessment that informed consent is not feasible." This agreement was apparently based on DOD officials' promise to "provide and disseminate additional information to all military personnel concerning the risks and benefits of pyridostigmine."[84]

Although FDA agreed to waive informed consent for both the pyridostigmine bromide and the botulism vaccine, the Assistant Secretary of Defense for Health Affairs notified Dr. Kessler on March 15, 1992, that "Central Command" had decided that the vaccine would be administered on a *voluntary* basis.[85] However, based on interviews with 150 Persian Gulf War veterans by Committee staff (Appendix), 88 percent of those who said they received a botulism vaccine were told they had no choice.

According to the DOD, all 696,562 U.S. troops in the Persian Gulf War were *issued* pyridostigmine bromide as a pretreatment for nerve agent poisoning, and officials estimate that approximately two-thirds *took* the drug for varying periods of time. Of 150 who were interviewed by Committee staff, 73 took pyridostigmine and 74

[82]Ibid.

[83]55 Federal Register 52,814-52,817 (December 21, 1990).

[84]Letter in Committee files.

[85]Letter from Enrique Mendez, Jr., M.D., to David Kessler, M.D., Commissioner, Food and Drug Administration, March 15, 1991; in Committee files.

percent of them were told they could not refuse to take it. Approximately 8,000 individuals received botulinum toxoid in the Persian Gulf. Given the high proportion who have reported that they had no choice, it appears that hundreds of thousands of U.S. troops were ordered to take an investigational drug or vaccine without having the opportunity to refuse.

2. Military personnel were not informed about the risks of the investigational drugs

Although DOD officials convinced FDA they need not offer choice, DOD had promised to provide extensive information about potential risks orally and in writing. In addition to being ordered to take an investigational product without informed consent, most Persian Gulf War military personnel surveyed claim they received no oral or written information about the drug or vaccine, despite the DOD promises to FDA to provide information about potential risks. These claims are supported by a survey conducted by the Department of Defense following the Persian Gulf War. Sixteen of 23 selected Persian Gulf War medical personnel surveyed by the DOD indicated that no information on the side effects of pyridostigmine bromide was provided to those who were ordered to take the drug.[86] These medical personnel were responsible for 8,366 military personnel during the Persian Gulf War.

There are two kinds of risks associated with lack of information. One is a lack of trust. In the survey conducted by Committee staff, 14 of 73 (19 percent) Persian Gulf War veterans who had been ordered to take pyridostigmine bromide indicated that they did not take all the pyridostigmine bromide they were ordered to take, fearful that the drug was responsible for the symptoms they experienced (Appendix). Because no one would answer their questions about the safety and efficacy of the pyridostigmine bromide, they feared they were receiving a potentially harmful drug. Therefore, if pyridostigmine bromide had been crucial for surviving nerve agent exposure, an unknown number of individuals would have lacked protection because they had received inadequate information about the drug.

The other risk is that even if serious side effects were rare, they could have been treated if medical personnel were able to diagnose the problem. For example, Carol Picou, a nurse who was stationed in the Gulf for 5 months, had obvious side effects from the pyridostigmine starting on the third day that she took it. These side effects included incontinence, drooling, and blurry vision, among others. The side effects became worse 1 hour after she took each pill. One day, she did not take the pill as scheduled, and the side effects stopped; unfortunately, her commanding officer ordered her to continue taking the pills, and watched to make sure she swallowed them. She was ordered to take the pills for 15 days. She now has many permanent medical problems, including incontinence, muscle

[86]Survey #1, Food and Drug Administration IND 23,509, Operation Desert Storm/Shield, May 27, 1992.

weakness, and memory loss, that might have been avoided had she been allowed to stop taking the pills.[87]

Similarly, Lt. Col. Neil Tetzlaff had immediate side effects when he started taking pyridostigmine bromide on the plane ride over to Saudi Arabia. His nausea and vomiting became so severe that he needed emergency surgery to repair a hole in his stomach. When he became ill, the military doctor told him to continue to take the pills, because the doctor apparently did not know that nausea and vomiting were known side effects. According to Tetzlaff's sworn testimony, the doctor acted as if the pyridostigmine was as safe as a cough drop.[88]

Civilians in the Gulf War

Numerous civilians have reported to Committee staff that they also were given investigational drugs during the Persian Gulf War without informed consent. For example, civilians who worked for DOD contractors and news media personnel were apparently instructed to take the pyridostigmine bromide tablets. They usually were not told it was experimental or that the pyridostigmine bromide was being administered in a regime that was not proven efficacious or safe, and received no information on potential side effects of the drug.

For example, according to journalists who covered the Gulf War, some were given the pills by the U.S. military. Several of these journalists experienced serious medical problems similar to Persian Gulf War veterans.[89] The Committee has also received letters from civilians who are suffering from "Gulf War syndrome" who report the widespread use of pyridostigmine by civilians working for DOD during the Gulf War.

Other Studies of Pyridostigmine

Following the Committee's May 6, 1994, hearing, several individuals who were in the Air Force during the 1980's contacted Committee staff to report they had also received pyridostigmine bromide without their consent.[90] They indicated that they did not volunteer for any research study, were ordered to take the pyridostigmine pills as part of a research project, and were ordered to report any side effects to the flight surgeons. One individual estimated that several hundred individuals in his squadron participated in the pyridostigmine studies, and reported that the studies were conducted over a period of at least 2 years.

The descriptions of these studies are disturbing because, if accurate, they indicate that even during peacetime, the Air Force totally ignored the requirements of informed consent that are a central provision of the Nuremberg Code, the Declaration of Helsinki,

[87]Response to Committee survey completed by Carol Picou, Persian Gulf War nurse; in Committee files.

[88]Hearing, May 6, 1994; statement of Neil Tetzlaff, Persian Gulf War veteran.

[89]Memoranda describing phone conversations with journalists are in Committee files.

[90]Letters, summaries of phone conversations, and supporting documents are in Committee files. These include an "Aircrew Symptoms Checklist on AF Form 1666 (TEST) FEB 86, which instructs the pilots to "[t]ake one (1) pyridostigmine bromide tablet (30 mg) every eight (8) hours over a 24 hour period."

and the "Common Rule" which had been in effect in at least some U.S. Government agencies at the time.

In addition to being unethical, these studies were reportedly unscientific; there were apparently no safeguards to ensure that the pilots took the pills or accurately reported the side effects. Many pilots who participated in these studies were on flight status; if they reported any side effects, they could lose their flight pay.[91] Obviously, this provided an incentive for them *not* to report any side effects, since they did not want to lose their flight pay. Similarly, those who experienced side effects had an incentive to stop taking the drug without notifying the researchers conducting the study. Moreover, pilots who contacted the Committee staff reported that many of their friends and colleagues did not take any of the pills at all, and many of those who did take at least one pill stopped taking them when they experienced headaches and other side effects. Despite the pressure to obey orders, many of the pilots apparently believed that they should not trust the Pentagon regarding the safety of these experimental pills.

One member of the air crew who was given pyridostigmine as part of these studies, Craig Crane, notified the Committee that he now has memory loss, joint pain, sensitivity to chemicals, and other symptoms that are commonly associated with Gulf War syndrome, although he is only 32 years old and did not serve in the Gulf War. He has left the Air Force because of his disabilities.[92]

C. DOD INCORRECTLY CLAIMS THAT SINCE THEIR GOAL WAS TREATMENT, THE USE OF INVESTIGATIONAL DRUGS IN THE PERSIAN GULF WAR WAS NOT RESEARCH.

Despite the fact that pyridostigmine was an investigational drug whose safety and effectiveness had not been proven to FDA, the DOD claims that its use in the Persian Gulf War was prevention and treatment, not research. For example, Dr. Edward Martin, Acting Principal Assistant Secretary of Defense for Health Affairs, stated at the Committee's hearing on May 6, 1994, that "..investigational products were employed during the Persian Gulf War as prophylactic treatments against biological and chemical warfare agents. This was not research but direct prevention and treatment."[93] Additionally, John M. Bachkosky, Deputy Director, Office of the Director of Defense Research and Engineering, wrote to Sen. Rockefeller on May 19, 1994, that "[botulinum toxoid and pyridostigmine bromide] were used

[91]One of the men has provided records of these studies to the Committee; although the records specify that all pilots participating in the study were removed from flight status and given informed consent about the risks of pyridostigmine, those records are not consistent with the descriptions of the study provided by the pilots who contacted the Committee. Moreover, the records themselves do not include an informed consent form or information about the risks of pyridostigmine.

[92]Letter and medical records of Craig Crane are in Committee files.

[93]Hearing, May 6, 1994; statement of Dr. Edward Martin, Acting Principal Assistant Secretary of Defense for Health Affairs.

for direct prevention and treatment and were not employed as part of any research effort."[94]

In a letter to Sen. Rockefeller dated November 17, 1994, DOD continues to claim that its use of pyridostigmine was not research. John Deutch, Deputy Secretary of Defense, wrote that, "Although pyridostigmine and botulinum toxoid were classified as investigational drugs as required by FDA regulations, they were not used for experimental purposes in [Operation Desert Storm] and the military personnel who received these products were not experimental subjects."[95] Mr. Deutch added that, "The fact that these drugs were used for treatment purposes, not research purposes, was clearly understood by all parties involved and specifically approved by the courts in litigation challenging the governments [sic] actions." Once again, it appears that the DOD confuses the goals of using these medical products with the process, which was clearly considered investigational by FDA.

Dr. Arthur Caplan, who at the time he testified was Director of the Center of Biomedical Ethics at the University of Minnesota, addressed that issue at the May 6 hearing. He explained that the fact that the goal is treatment and that DOD believed the benefits of the pills and vaccines would outweigh the risks "doesn't transform the use of experimental, innovative, investigational agents into therapies. These agents were used, as we have heard, in large populations for purposes other than those for which they were originally designed in some cases, and circumstances under which they had never before been tried out in the desert. This seems to me to cinch the case that what took place fell into the category of experimental, innovative and investigational, and that makes them research."[96]

Since the end of the Persian Gulf War, DOD has repeatedly requested that the waiver of informed consent be made permanent, arguing that "to not finalize it provides an arguable defect under the Administrative Procedures Act and leaves both DOD and FDA open to greater liability."[97] To finalize the interim rule would grant unrestricted use of investigational drugs by military personnel, even though investigational status means that efficacy and safety have not been proven. FDA has not yet decided whether to concur with DOD's request.

D. DOD USED INVESTIGATIONAL DRUGS IN THE PERSIAN GULF WAR IN WAYS THAT WERE NOT EFFECTIVE.

The DOD persuaded FDA that informed consent should be waived for pyridostigmine bromide and botulism vaccine because these

[94]Letter from John M. Bachkosky, Deputy Director, Office of the Director of Defense Research and Engineering, U.S. Department of Defense, to Sen. John D. Rockefeller IV, Chair, Senate Committee on Veterans' Affairs, May 19, 1994.

[95]Letter from John Deutch, Deputy Secretary of Defense, to Sen. John D. Rockefeller IV, Chair, Senate Committee on Veterans' Affairs, November 17, 1994; in Committee files.

[96]Hearing, May 6, 1994; statement of Arthur Caplan, Ph.D. Dr. Caplan is now Director of the Center of Biomedical Ethics at the University of Pennsylvania.

[97]Minutes, Meeting (July 27, 1992) on Finalizing Interim Rule on Waiver of Informed Consent, signed July 28, 1992, by William H. Habig.

investigational products had been used safely in the past. However, based on documents provided to the Committee staff, it is doubtful that either of these products would have been effective as used in the Persian Gulf War.

Pyridostigmine bromide, according to DOD, improves the survival of animals exposed to soman and treated with atropine and 2-PAM. However, pyridostigmine pretreatment makes individuals more vulnerable to other nerve agents, such as VX and sarin.[98] The DOD scientists who studied pyridostigmine and *sarin* therefore concluded that pyridostigmine should *only* be used when the chemical warfare threat is *soman*.[99]

The Pentagon, however, had no reason to believe that the Iraqis were more likely to use soman rather than sarin. According to a report by the Persian Gulf Veterans Coordinating Board, Iraq had several chemical weapons, including sarin.[100] Moreover, at a briefing for Senators and staff on November 10, 1993, Under Secretary of Defense John Deutch stated that the Czechoslovakian military detected low levels of *sarin* in the Saudi theater during the opening days of the air war against Iraq. This statement was also made by Joseph Corrivean, U.S. Army Foreign Science and Technology Center, on April 27, 1994, at a National Institutes of Health workshop on "The Persian Gulf Experience and Health."

Even if U.S. troops had been exposed to soman, it is unclear that the pyridostigmine would have provided adequate protection against nerve damage. When DOD began the second phase of research on pyridostigmine, it was noted that the atropine and 2-PAM did not seem to save the lives of animals that were exposed to soman. As a result, the dose of atropine was increased to 0.40 mg/kg, which according to FDA, increased the survival of Rhesus monkeys exposed to soman.[101] However, when the Department of Defense developed a treatment regimen for U.S. troops during the Persian Gulf War, it was based on the *inadequate* dose of atropine in the animal studies (0.096 mg/kg) rather than the higher, effective dose.[102] **Therefore, even if Persian Gulf soldiers had been exposed to soman, it is questionable if the pyridostigmine pretreatment would have provided any protection, since the dose of atropine was apparently inadequate.**

In response to posthearing questions about this dosage discrepancy from Sen. Rockefeller, the DOD stated "the dose of atropine in the Mark I kit was established based exclusively on safety, rather than

[98]Koplovitz, I., Harris, L.W., Anderson, D.R., Lennox, W.J., & Stewart, J.R. "Reduction by pyridostigmine pretreatment of the efficacy of atropine and 2-PAM treatment of sarin and VX poisoning in rodents," *Fundamental and Applied Toxicology*, Vol. 18, 1992, pp. 102-106.

[99]Sidell, F.R., op. cit.

[100]"Summary of the issues impacting upon the health of the Persian Gulf veterans," Version 1.1: March 3, 1994.

[101]The actual data from this study was not provided to our Committee, and apparently not provided to FDA either.

[102]IND Amendment, Reference to IND# 28480, March 28, 1988, Letter from Thomas H. Gray, Chief, Operational Unit Training Branch, Department of the Air Force, to Mr. David Banks, Consumer Safety Officer, FDA.

on efficacy, considerations."[103] This statement suggests that hundreds of thousands of servicemembers were put at risk by requiring them to take a drug with known risks (pyridostigmine bromide) in a situation where it might have done little good since the *atropine* dose in the Mark I kits, 6 mg, was inadequate. Based on the monkey data, a dose of 27 mg would have been required for a 150-pound man.[104] However, the side effects of only 2 mg of atropine in a normal young person (without nerve-agent exposure) include increased heart rate, decreased sweating, visual blurring, and others.[105] Apparently, DOD officials decided that the high dosage required for protection would impair performance, so they selected the much lower dosage, even though its effectiveness was questionable. Although results for monkeys may not be exactly comparable to those for humans, it seems unlikely that humans would respond dramatically differently. It is therefore likely that the dose of atropine in the Mark I kits was inadequate for efficacy, and even with this very low dose could have compromised the ability of servicemembers during war.[106]

Botulism vaccine was given too late to U.S. troops to be of any use had the Iraqis actually used biological warfare during Desert Storm. At a briefing on April 20, 1994, DOD officials informed Committee staff that botulism vaccine was not administered to most military personnel in the Persian Gulf until January 23, 1991, which was 7 days *after* the onset of the air war. Approximately 8,000 individuals received the vaccine, but most received only one or two inoculations. Because the war ended on February 27, 1991, before the third injection was scheduled to be given, it is unlikely that these soldiers were adequately immunized. Moreover, because of the severe shortage of the product, the remainder of those deployed received no inoculations, and hence no protection against botulism.

According to the Department of Veterans Affairs, 696,562 individuals participated in Operation Desert Shield/Desert Storm. **Therefore, 99 percent of the military personnel deployed would have received no protection due to the shortage of botulinum toxoid, and the remaining 1 percent were probably not protected because the vaccine distribution started too late.**

Additionally, in December 1990, the FDA advised the Department of Defense that it would be unable to test the botulism vaccine for efficacy, presumably because of limited time before the onset of the war.[107] Therefore, in addition to the limited supply of vaccine and late

[103]Answers from the Department of Defense to followup questions submitted by Sen. John D. Rockefeller IV, after the Committee's May 6, 1994, hearing. The answers were received by the Committee on September 19, 1994.

[104]A 150-pound man weighs 68 kg; 68 x 0.4 = 27 mg.

[105]Sidell, F.R., op. cit.

[106]The administration of additional atropine some hours after exposure to chemical weapons might have been helpful, but it is not clear how many soldiers would have been fortunate enough to receive medical treatment within hours of combat, or how effective that later treatment would have been.

[107]Minutes of Meeting of the Informed Consent Waiver Review Group (ICWRG), Food and Drug Administration, December 31, 1990.

onset of inoculations, efficacy of the existing supply was not determined prior to the onset of the war.

Anthrax vaccine was given to approximately 150,000 military personnel in the Persian Gulf. Anthrax vaccine is considered effective for protecting against anthrax exposure of the skin; however it is unclear whether it provides protection against inhaling aerosolized anthrax.[108] According to the Department of Defense, in biological warfare the anthrax would be sprayed, so the efficacy of the vaccine against aerosolized anthrax would have been the relevant test.[109] As stated earlier in this report, the DOD has only one study indicating that the vaccine might be useful against aerosolized anthrax, but there are no data on humans.

E. DOD DID NOT KNOW WHETHER PYRIDOSTIGMINE BROMIDE WOULD BE SAFE FOR USE BY U.S. TROOPS IN THE PERSIAN GULF WAR.

Committee staff reviewed all the clinical studies and related research regarding pyridostigmine on healthy individuals which DOD provided to FDA to support their IND and their NDA (new drug approval) application.[110] The number of human subjects in most studies was less than 35; several studies included as few as two or four individuals.

According to the materials that FDA provided to the Committee, virtually all the studies excluded women. The lack of studies on women is a problem, because dosage should be based on the weight of the person taking the drug, and because some scientists believe that pyridostigmine may affect men and women differently.[111,112] For example, women on birth control pills may have different levels of AChE than other women or men. Similarly, women in different stages of their reproductive cycle respond differently to pyridostigmine.[113] Since studies excluded women, there is no information on the potential long-term side effects of pyridostigmine on diseases unique to women (such as menstrual cycle irregularities or breast cancer).

Because of the DOD researchers' concerns about serious adverse reactions to pyridostigmine bromide, many of the studies screened the men to determine whether they were hypersensitive to pyridostigmine bromide before allowing their participation in the experiment. In some cases they used test doses; in other cases they asked questions regarding similar medications and sensitivity to bromide. In many of the studies, patients were excluded if they were taking any

[108]In a letter dated July 27, 1992, FDA asked whether an IND should be required to test the anthrax vaccine against aerosolized anthrax.

[109]Department of Defense briefing with staff of the Senate Committee on Veterans' Affairs, 414 Russell Senate Office Building, April 20, 1994.

[110]A list of many of these studies is in Appendix A.

[111]Barbarino, A., Corsello, S.M., Tofani, A., et al. "Sexual dimorphism of pyridostigmine potentiation of growth hormone (GH)-releasing hormone-induced GH release in humans," *Journal of Clinical Endocrinology and Metabolism*, Vol. 73, No. 1, 1991, pp. 75-78.

[112]O'Keane V. & Dinan, T.G. "Sex steroid priming effects on growth hormone response to pyridostigmine throughout the menstrual cycle," *Journal of Clinical Endocrinology and Metabolism*, Vol. 75, No. 1, 1992, pp. 11-14.

[113]Ibid.

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Human Experimentation

An Overview on Cold War Era Programs

Statement of Frank C. Conahan, Assistant Comptroller General, National Security and International Affairs Division

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Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the use of humans in tests and experiments conducted for national security purposes by the Department of Defense (DOD) and other agencies between 1940 and 1974. As you requested, we collected information on the scope of these experiments and their possible impact. We obtained information on (1) the magnitude and scope of human subject experimentation, (2) the potential effects of the experiments on human subjects, (3) government efforts to assist those who may have been injured or suffered adverse health effects as a result of the tests or experiments, and (4) measures to ensure that informed consent is secured and that volunteers are protected in government-sponsored experiments.

BACKGROUND

As you requested, we focused our work on defense-affiliated programs that used human test subjects between 1940 and 1974. The programs included tests and experiments conducted or sponsored by the Departments of the Army, the Navy, and the Air Force; the Defense Nuclear Agency; the Central Intelligence Agency (CIA); the Department of Energy; and the Department of Health and Human Services. The tests and experiments involved radiological, chemical, and biological research and were conducted to support weapon development programs, identify methods to protect the health of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities.

RESULTS IN BRIEF

During World War II and the Cold War era, DOD and other national security agencies conducted or sponsored extensive radiological, chemical, and biological research programs. Precise information on the number of tests, experiments, and participants is not available, and the exact numbers may never be known. However, we have identified hundreds of radiological, chemical, and biological tests and experiments in which hundreds of thousands of people were used as test subjects. These tests and experiments often involved hazardous substances such as radiation, blister and nerve agents, biological agents, and lysergic acid diethylamide (LSD). In some cases, basic safeguards to protect people were either not in place or not followed. For example, some tests and experiments were conducted in secret; others involved the use of people without their knowledge or consent or their full knowledge of the risks involved.

The effects of the tests and experiments are often difficult to determine. Although some participants suffered immediate acute injuries, and some died, in other cases adverse health problems were not discovered until many years later--often 20 to 30 years or longer.

Federal programs provide benefits to former military and federal civilian employees who suffer from injuries or adverse health effects as a result of federal service. However, it has proven difficult for participants in government tests and experiments between 1940 and 1974 to pursue claims because little centralized information is available to prove participation or determine whether adverse health effects resulted from the testing. To address these problems, special efforts have been made by some involved agencies to help groups of test participants obtain the information necessary to pursue claims. For example, the Department of Veterans Affairs (VA) relaxed its requirement that participants link their health problems to those tests or experiments. Also, since 1978 DOD has had a program to identify and provide information to participants in atmospheric nuclear tests that were conducted between the 1940s and 1960s. More recently, in January 1994, the administration established an advisory committee to identify participants in other government-sponsored radiation research. We are reviewing the efforts of the committee at the request of the Senate Committee on Governmental Affairs.

In other areas, however, special efforts to make information available on test participants are not as far along. For example, DOD recently recognized a need to identify and assist participants in chemical tests conducted prior to 1968, but to date limited resources have been applied. We were told earlier this month that the VA continues to have difficulty processing claims because it cannot obtain necessary information from DOD. Some participants or their survivors have pursed benefits or compensation, outside existing federal programs, through specific congressional action or court awards.

Although military regulations in effect as early as 1953 generally required that volunteers be informed of the nature and foreseeable risks of the studies in which they participated, this did not always occur. Some participants have testified that they were not informed about the test risks. Government testing and experimentation with human subjects continues today because of its importance to national security agencies. For example, the Army's Medical Research Institute for Infectious Disease uses volunteers in its tests of new vaccines for malaria, hepatitis, and other exotic diseases. Since 1974, federal regulations have become more protective of research subjects and, in general, require (1) the formation of institutional review boards and procedures and (2) researchers to obtain informed consent from human subjects and ensure that their participation is voluntary and based on knowledge of the potential risks and benefits. We are in the process of reviewing the effectiveness of these measures. A National Institutes of Health official has stated that no mechanism exists to ensure implementation of the key federal policies in this area.

THE GOVERNMENT HAS SPONSORED EXTENSIVE TESTING, BUT PRECISE INFORMATION ON TESTS AND PARTICIPANTS IS NOT AVAILABLE

Precise information on the scope and magnitude of government tests and experiments involving human subjects is not available, and exact numbers may never be known. However, our review of available documentation and interviews with agency officials identified hundreds of tests and experiments in which hundreds of thousands of people were used as subjects. Some of these tests and experiments involved the intentional exposure of people to hazardous substances such as radiation, blister and nerve agents, biological agents, LSD, and phencyclidine (PCP). These tests and experiments were conducted to support weapon development programs, identify methods to protect the health of military personnel against a variety of diseases and combat conditions, and analyze U.S. defense vulnerabilities. Healthy adults, children, psychiatric patients, and prison inmates were used in these tests and experiments.

Documenting the precise number of tests and participants is difficult because government information is incomplete. Some records have been lost or destroyed, and existing documentation contains limited information and often does not identify names of participants. Moreover, these records are spread throughout the country at the National Archives, Federal Record Centers, other government offices, and the military commands or organizational units that created them. Some of the records measure thousands of linear feet, and the availability and quality of indexes to the records vary widely.

I will describe a few of the radiological, chemical, and biological research projects that illustrate the scope and magnitude of governmental experimentation.

Radiological Tests and Experiments

To date, over 200 radiation tests and experiments have been identified involving over 210,000 test participants. Although not involved in a test or experiment, another 199,000 people were exposed to radiation through work. This latter group is of concern because the effects of the exposure are the same as those incurred by test participants. The radiation tests are generally recognized as involving the largest number of test participants.

The largest known test program was the atmospheric nuclear test program conducted from 1945 to 1962. The purpose of this program was to develop weapons and to gain a better understanding of the tactical effect on troops. Over this 17-year period, approximately 210,000 DOD-affiliated personnel, including civilian employees of DOD contractors, scientists, technicians, maneuver and training troops, and support personnel, participated in 235 atmospheric nuclear tests. We reported on two of these tests, known as

Operation Crossroads, in 1985.[1] In some tests, participants were directly exposed to radiation. For example, in one test, five individuals were located directly beneath a high-altitude test. In other tests, 37 individuals were located in trenches from 2,000 to 2,600 yards from ground zero, and in others, approximately 26,000 individuals occupied trenches, bunkers, and armored vehicles from 2,500 to 5,500 yards from ground zero. According to DOD officials, as many as 150,000 of the 210,000 participants may have been exposed to fallout. In addition, 195,000 U.S. service members may have been exposed to radiation during the occupation of Hiroshima and Nagasaki, and over 4,000 other service members may have been exposed during cleanups at Bikini, Enewetak, and Johnston Atolls after nuclear tests were conducted. Some participants have alleged that they were not fully informed or did not understand the potential health risks of exposure to radiation.

In a series of experiments conducted between the 1940s and 1960s, the Atomic Energy Commission and the U.S. Public Health Service funded research of the potential medical effects on people from fallout after a nuclear attack or accident. In some of the experiments, university researchers exposed mentally disabled children to low doses of radiation. Years after the experiments were completed, a task force found that researchers failed to satisfactorily inform the subjects' families about the nature and risk of the experiments in order for them to make an informed decision when they gave their consent. The president of one of the universities involved in the experiments later apologized for the use of children and the failure to provide full information about the nature and risk. We are not aware of what, if any, further action was taken in this case.

Chemical Tests and Experiments

During World War II and the Cold War era, the Army and the Navy conducted two major chemical research experiments in which thousands of service members were used as test subjects. An unknown number of other chemical tests and experiments were conducted under contracts with universities, hospitals, and medical research facilities. In some of the tests and experiments, healthy adults, psychiatric patients, and prison inmates were used without their knowledge or consent or their full knowledge of the risks involved.

During World War II, the Army conducted tests of protective clothing and equipment in which thousands of people were exposed to mustard gas and lewisite agents. In addition, the Army developed and tested offensive chemical weapons and evaluated the effectiveness and persistency of mustard agents in different

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[1]Operation Crossroads: Personnel Radiation Exposure Estimates Should Be Improved (GAO/RCED-86-15, Nov. 8, 1985).