### CENTERS FOR DISEASE CONTROL AND PREVENTION DEPARTMENT OF HEALTH AND HUMAN SERVICES

## ORDER UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT (42 U.S.C. § 264) AND 42 CODE OF FEDERAL REGULATIONS §§ 71.20 & 71.31(b)

# REQUIREMENT FOR NEGATIVE PRE-DEPARTURE COVID-19 TEST RESULT OR DOCUMENTATION OF RECOVERY FROM COVID-19 FOR ALL AIRLINE OR OTHER AIRCRAFT PASSENGERS ARRIVING INTO THE UNITED STATES FROM ANY FOREIGN COUNTRY<sup>1</sup>

#### **SUMMARY**:

Pursuant to 42 C.F.R. § 71.20 and as set forth in greater detail below, this Notice and Order prohibit the introduction into the United States of any aircraft passenger departing from any foreign country unless the passenger: (1) has a negative pre-departure test result for SARS-CoV-2, the virus that causes COVID-19 (Qualifying Test); or (2) written or electronic documentation of recovery from COVID-19 after previous SARS-CoV-2 infection in the form of a positive viral test result and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery).

The negative pre-departure test must be a viral test that was conducted on a specimen collected during the 3 calendar days preceding the flight's departure from a foreign country (Qualifying Test). Alternatively, if the passenger has recovered from COVID-19, the passenger may instead travel with written or electronic documentation of a positive viral test result that confirms previous SARS-CoV-2 infection and a letter from a licensed health care provider or public health official stating that the passenger has been cleared for travel (Documentation of Recovery). A passenger must retain written or electronic documentation reflecting the negative Qualifying Test result or Documentation of Recovery presented to the airline or other aircraft operator. A passenger must also produce such Qualifying Test result or Documentation of Recovery upon request to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 C.F.R. § 71.31(b) and as set forth in greater detail below, this Notice and Order constitute a controlled free pratique to any airline or other aircraft operator with an aircraft arriving into the United States. Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the following conditions to receive permission for the aircraft to enter and disembark passengers in the United States:

<sup>&</sup>lt;sup>1</sup> This Order supersedes the previous order signed by the U.S. Centers for Disease Control and Prevention (CDC) Director on December 25, 2020, requiring a negative pre-departure COVID-19 test result for all airline passengers arriving into the United States from the United Kingdom.

- Airline or other aircraft operator must verify that every passenger—2 years of age or older—onboard the aircraft has attested to receiving a negative Qualifying Test result or to having recovered from COVID-19 after previous SARS-CoV-2 infection and being cleared to travel by a licensed health care provider or public health official.
- Airline or other aircraft operator must confirm that every passenger onboard the aircraft
  has documentation of a negative Qualifying Test result or Documentation of Recovery
  from COVID-19.

#### STATEMENT OF INTENT:

This Order shall be interpreted and implemented to achieve the following paramount objectives:

- Preservation of human life;
- Preventing the further introduction, transmission, and spread of the virus that causes COVID-19 into the United States, including new virus variants;
- Preserving the health and safety of crew members, passengers, airport personnel, and communities; and
- Preserving hospital, healthcare, and emergency response resources within the United States.

#### **DEFINITIONS:**

Aircraft shall have the same definition as under 42 U.S.C. § 40102(a)(6). "Aircraft" includes, but is not limited to, commercial, general aviation, and private aircraft destined for the United States from a foreign country.

Aircraft Operator means an individual or organization causing or authorizing the operation of an aircraft.

Airline shall have the same definition as under 42 C.F.R. § 71.1(b).

*Attest/Attestation* means having completed the attestation in Attachment A. Such attestation may be completed in written or electronic form. The attestation is a statement, writing, entry, or other representation under 18 U.S.C. § 1001.<sup>2</sup>

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<sup>&</sup>lt;sup>2</sup> CDC encourages airline or aircraft operator to incorporate the attestation into paperless check-in processes. Airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. But airline or aircraft operator has sole legal responsibility to provide and collect attestations, to ensure the accuracy of any translation, and to comply with all other obligations under this Order. Airline or aircraft operator is responsible for any failure of a third party to comply with this Order. Airline or aircraft operator may not shift any legal responsibility to a third party.

Confirm that every passenger onboard the aircraft has documentation reflecting a negative Qualifying Test result means confirmation that:

- 1) the personal identifiers (e.g., name and date of birth) on the negative Qualifying Test result match the personal identifiers on the passenger's passport or other travel documents;
- 2) if the passenger is arriving on a direct flight to the United States, the specimen was collected within the 3 calendar days preceding the flight's departure;
- 3) if the passenger is arriving via one or more connecting flights, the specimen was collected within the 3 calendar days preceding the departure of the initial flight but only if
  - a. the connecting flights were booked as a single passenger record with a destination in the United States,
  - b. each connection is no longer than 24 hours, and
  - c. the airline or aircraft operator has instructed the passenger to comply—and uses reasonable efforts to facilitate compliance—with the safety protocols set forth in Runway to Recovery 1.1, December 21, 2020, available at <a href="https://www.transportation.gov/briefing-room/runway-recovery-11">https://www.transportation.gov/briefing-room/runway-recovery-11</a>, during such connection(s);
- 4) the test performed was a viral test (as defined below); and
- 5) the test result states "NEGATIVE," "SARS-CoV-2 RNA NOT DETECTED," "SARS-CoV-2 ANTIGEN NOT DETECTED," or "COVID-19 NOT DETECTED." A test marked "invalid" is not acceptable.

Confirm that a passenger alternatively has written or electronic documentation of recovery from *COVID*-19 means confirmation that:

- 1) the passenger has presented documentation of a positive test result and a signed letter on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official stating that the passenger has been cleared for travel;<sup>3</sup>
- 2) the positive test result occurred within the last three months (90 days) preceding the passenger's flight to the United States, or at such other intervals as specified in CDC guidance;
- 3) the personal identifiers (e.g., name and date of birth) on the positive test result and signed letter match the personal identifiers on the passenger's passport or other travel documents;
- 4) the test performed was a viral test (as defined below); and
- 5) the test result states "POSITIVE," "SARS-CoV-2 RNA DETECTED," "SARS-CoV-2 ANTIGEN DETECTED," or "COVID-19 DETECTED." A test marked "invalid" is not acceptable.

Foreign country means anywhere that is not a state, territory, or possession of the United States.

<sup>&</sup>lt;sup>3</sup> Health care providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html.

Negative Pre-departure Test Result for COVID-19 or negative Qualifying Test result means documentation of a negative COVID-19 test taken within the 3 calendar days preceding a flight's departure. Such documentation may be in paper or electronic format as required by this Order. Testing must be performed using a viral test. The documentation must also include sufficient verification information—such as the name and contact information for the laboratory or healthcare personnel who performed the test.

*Viral test* means a viral detection test for current infection (i.e., a nucleic acid amplification test or a viral antigen test) approved or authorized by the relevant national authority for the detection of SARS-CoV-2.

*United States* has the same meaning as "State" and "U.S. Territory" in 42 C.F.R. § 71.1(b).

#### **EXEMPTIONS:**

The following categories of individuals and organizations are exempt from the requirements of this Order:

- Crew members of airlines or other aircraft operators provided that they follow industry standard protocols for the prevention of COVID-19 as set forth in relevant Safety Alerts for Operators (SAFOs) issued by the Federal Aviation Administration (FAA).<sup>4</sup>
- Airlines or other aircraft operators transporting passengers with COVID-19 pursuant to CDC authorization and in accordance with CDC guidance.
- Federal law enforcement personnel while on official duty and carrying out a law enforcement function and members of the U.S. military (including aircraft operators), when traveling under competent orders—provided that the authority ordering the travel requires precautions to prevent the possible transmission of infection to others during the travel period in accordance with CDC guidance.
- Airlines or other aircraft operators granted specific waivers from the application of this Order based on CDC's determination that a foreign country lacks available SARS-CoV-2 testing capacity. Such waivers may be granted based on a specific request made by an

<sup>4</sup>https://www.faa.gov/other\_visit/aviation\_industry/airline\_operators/airline\_safety/safo/all\_safos/media/2020/SAFO20009.pdf. Airlines, aircraft operators, and their crew members may follow even stricter protocols for safety, including testing protocols.

airline or aircraft operator to the CDC and will be limited to 14 days unless renewed by CDC.<sup>5</sup>

#### **BACKGROUND:**

The COVID-19 pandemic has spread throughout the world. Individuals who travel may be at risk for exposure to SARS-CoV-2 before, during, and after travel. This could result in US-bound travelers further spreading the virus to others during travel, upon arrival in the United States, and at their destinations.

Over the last few weeks, the United Kingdom (UK) has faced a rapid increase in COVID-19 cases in South East England, leading to enhanced epidemiological and virological investigations. On December 14, 2020, Public Health England announced that a new variant of SARS-CoV-2 had been identified across the southeast of England.<sup>6</sup> Preliminary analysis in the UK suggests that this SARS-CoV-2 variant may be more transmissible than previously circulating variants, with an estimated potential to increase the reproductive number ( $R_0$ ) by 0.4-0.7 or greater with an estimated increased transmissibility of up to 70 percent.<sup>7</sup>

On December 19, 2020, in response to the emergence of the UK variant, the countries comprising the UK announced stricter measures to be applied from December 20 and over the coming weeks, with affected areas entering a 'Tier 4' level with movement restrictions within and between more and less heavily affected areas. These measures have included recommendations for residents of the most affected areas to restrict movements and travel, including international travel, outside of these areas. The government of Scotland announced a travel ban between Scotland and the rest of the UK. In addition, the Netherlands issued a travel ban from the UK effective through January 1, 2021, and Belgium temporarily halted flight and train travel from the UK. Other countries took similar measures to restrict travel from the UK.

A second new variant of SARS-CoV-2 was reported in the Republic of South Africa (RSA) on December 18, 2020, that also appears to spread more rapidly than earlier variants of the virus. The RSA variant is distinct from the UK variant but shares a mutation in the spike protein that appears to increase transmissibility. Since being identified, the new variant has spread inland from coastal regions of RSA and has become the predominant variant in some areas of the country.

During December 21-26, 2020, several countries implemented restrictions on travel from South

<sup>&</sup>lt;sup>5</sup> Based on the rapidly evolving status of laboratory testing capacity in foreign countries, CDC has determined that 14 days, subject to renewal, is an appropriate length of time to allow for a waiver.

<sup>&</sup>lt;sup>6</sup> https://www.gov.uk/government/news/phe-investigating-a-novel-variant-of-covid-19.

https://www.ecdc.europa.eu/en/publications-data/threat-assessment-brief-rapid-increase-sars-cov-2-variant-united-kingdom.

Africa, including China, El Salvador, Germany, Guatemala, Israel, Panama, Sudan, Switzerland, Turkey, and the UK. The Netherlands imposed a ban on travel from RSA on December 21 but lifted the ban for both the UK and RSA on December 23, stating that travelers will instead need to present a negative COVID-19 test result obtained within 72 hours of their scheduled arrival in the Netherlands, followed by 10 days of self-quarantine. On December 28, Japan imposed a ban on entry of all foreign nationals through the end of January 2021. On December 28, the Government of South Africa announced new restrictions on businesses and public movement. As of January 7, 2021, Canada requires air passengers 5 years of age or older to test negative for COVID-19 before arrival. On January 8, the United Kingdom announced a pre-departure testing requirement for all inbound international travelers with limited exceptions; a 10-day post-arrival quarantine will still be required.

On December 25, 2020, CDC issued an Order requiring proof of a negative Qualifying Test result for all airline passengers arriving from the UK to the United States. Since then, cases of the UK and RSA variants have been discovered in four Canadian provinces, including in individuals with no travel history indicating spread in Canada. The UK variant has also been found in at least 50 countries and the RSA variant has also been detected in at least 15 countries. The first case of the UK variant in the United States was found in Colorado on December 29, in an individual with no known travel history. On December 30, a second case was reported in California. Since then, the UK variant strain has accounted for 72 cases in 10 U.S. states. Another new variant strain of concern initially detected in South America in March 2020 has been detected in at least 19 countries on 5 continents through late December and has mutations in the spike protein that raise concerns of increased infectivity.

While it is known and expected that viruses constantly change through mutation leading to the emergence of new variants, these new variants have emerged at a time when numbers of new cases in the United States have continued to increase at alarming rates. Additional new virus variants are also likely to emerge as the virus continues to evolve and mutate. Accordingly, further action is needed to help mitigate the spread of these and other new virus variants into the United States.

Based on increased transmissibility and spread of these new variants of SARS-CoV-2, and to reduce introduction and spread of these and future SARS-CoV-2 variants into the United States, expanding current UK pre-departure testing requirements to all foreign countries and U.S.-bound passengers is warranted. This approach to testing-based risk assessment has been addressed in CDC guidance and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and Human Services. Testing for SARS-CoV-2 infection is a proactive approach and not dependent on the infecting strain. Approximately 120 countries now use testing in some form to monitor risk and control introduction and spread. With case counts and deaths due to COVID-19 continuing to increase around the globe and the high proportion of infected people with asymptomatic or pre-symptomatic infections, the United States

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<sup>&</sup>lt;sup>8</sup> Runway to Recovery 1.1, December 21, 2020, available at https://www.transportation.gov/briefing-room/runway-recovery-11

must take a dual approach to combatting the virus. This means concurrently mitigating and slowing the introduction and spread of SARS-CoV-2 and controlling transmission within U.S. communities that are currently being overwhelmed by a surge in infections, hospitalizations, and deaths.

Pre-departure testing may detect travelers infected with SARS-CoV-2 before they initiate their travel. CDC recommends viral testing and receipt of results 1-3 days<sup>9</sup> before departure for international travelers, particularly those traveling long distances or passing through transportation hubs such as airports where social distancing may be challenging. CDC modeling indicates that pre-departure testing is most effective when combined with self-monitoring.<sup>10</sup> Testing before departure results in the greatest reduction of transmission risk during travel when the specimen is collected close to the time of departure. Earlier testing (i.e., more than 3 days before travel) provides little benefit beyond what self-monitoring alone can provide.

For persons previously diagnosed with COVID-19 who remain asymptomatic after recovery, CDC does not recommended retesting within 3 months after the date of symptom onset (or the date of first positive viral diagnostic test if their infection was asymptomatic) for the initial SARS-CoV-2 infection. Persons who develop any symptoms of COVID-19 during this time period should not travel and seek care for testing and evaluation. This guidance may be updated as additional information about people who have recovered from COVID-19 becomes available.

Pre-departure testing does not eliminate all risk. However, when pre-departure testing is combined with other measures such as self-monitoring for symptoms of COVID-19, wearing masks, social distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations. For international air travelers and others with higher risk of exposure, CDC additionally recommends a post-arrival test 3-5 days after arrival at destination, combined with self-monitoring and a 7-day period of staying home (or in a comparable location such as a hotel room) to further reduce the risk of translocating the virus into destination communities.<sup>12</sup>

As cases of COVID-19 continue to rise across the globe and travel volume increases, routine predeparture testing of all U.S.-bound aircraft passengers is needed not only to reduce introduction of the two known SARS-CoV-2 variants from UK and RSA, but also future variants that might be more transmissible and cause more severe illness.

<sup>&</sup>lt;sup>9</sup> https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html.

<sup>&</sup>lt;sup>10</sup> Johansson MA, Wolford H, Paul P, et al. Reducing travel-related SARS-CoV-2 transmission with layered mitigation measures: Symptom monitoring, quarantine, and testing, *available at* https://www.medrxiv.org/content/10.1101/2020.11.23.20237412v1.

<sup>&</sup>lt;sup>11</sup> https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

<sup>12</sup> https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html

#### ACTION:

For these reasons, I hereby determine that passengers covered by this Order are at risk of transmitting the new SARS-CoV-2 virus variants or other potential variants and that requiring such passengers to demonstrate either negative COVID-19 test results or recovery from COVID-19 after previous SARS-CoV-2 infection is needed as a public health measure to protect the health of fellow travelers and U.S. communities.

#### 1. Requirements for Airlines & Other Aircraft Operators

Any airline or other aircraft operator with passengers arriving into the United States from a foreign country, for each passenger onboard the aircraft arriving into the United States, shall —

- a. Verify that each passenger has attested to having received either a negative Qualifying Test result or to recovery from COVID-19 after previous SARS-CoV-2 infection and clearance to travel. Airlines or other aircraft operators must retain a copy of each passenger attestation for 2 years. The attestation is attached to this order as Attachment A.
- b. Confirm that each passenger aged 2 years or older has documentation of a negative Qualifying Test result or Documentation of Recovery from COVID-19.
- c. Not board any passenger without verifying the attestation and confirming the documentation as set forth in 1.a-b.

Any airline or other aircraft operator that fails to comply with section 1, "Requirement for Airlines & Other Aircraft Operators," may be subject to criminal penalties under, *inter alia*, 42 U.S.C. § 271 and 42 C.F.R. § 71.2, in conjunction with 18 U.S.C. §§ 3559 and 3571.

#### 2. Requirements for Aircraft Passengers

Any aircraft passenger departing from any foreign country with a destination in the United States shall —

a) Provide an attestation to the CDC, through the airline or other aircraft operator, of having received a negative Qualifying Test result or of recovery from COVID-19 after previous SARS-CoV-2 infection and clearance to travel. The attestation is attached to this order as Attachment A. Unless otherwise permitted by law, a parent or other authorized individual should attest on behalf of a passenger aged 2 to 17 years. An authorized individual may attest on behalf to any passenger who is unable to attest on his or her own behalf (e.g., by reason of physical or mental impairment).

b) Retain a copy of the negative Qualifying Test result or Documentation of Recovery from COVID-19 in his/her possession and present it for inspection to the airline and upon request by an agent of the U.S. government or a cooperating state or local public health authority.

Any passenger who fails to comply with the requirements of section 2, "Requirements for Aircraft Passengers," may be subject to criminal penalties under, *inter alia*, 42 U.S.C. § 271 and 42 C.F.R. § 71.2, in conjunction with 18 U.S.C. §§ 3559 and 3571. Willfully giving false or misleading information to the government may result in criminal penalties under, *inter alia*, 18 U.S.C. § 1001.

CDC may modify this Order by an updated publication in the Federal Register or by posting an advisory to follow at www.cdc.gov.

This Order shall be enforceable through the provisions of 18 U.S.C. §§ 3559, 3571; 42 U.S.C. §§ 243, 268, 271; and 42 C.F.R. § 71.2.

#### **EFFECTIVE DATE:**

This Order shall enter into effect on January 26, 2021 and shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) December 31, 2021.

Dated: January 12, 2021.

Porent R. Ruffeelel VS

Robert Redfield, M.D.

Director, Centers for Disease Control and Prevention