# CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

NOTICE AND AMENDED 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)

REQUIREMENTS 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

#### SUMMARY:

Pursuant to 42 CFR 71.20 and 71.31(b) and as set forth in greater detail below, this Notice and Amended Order prohibits the boarding of any passenger - 2 years of age or older - on any aircraft destined to the United States<sup>1</sup> from a foreign country unless the passenger<sup>2</sup>:

 $<sup>^{\</sup>scriptsize 1}$  This includes any flight regardless of whether the United States is the final destination or a connection to another country.

<sup>&</sup>lt;sup>2</sup> A parent or other authorized individual may present the required documentation on behalf of a passenger 2-17 years of age. Children under the age of 2 years of age are not subject to the requirements of this Amended Order. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (e.g., by reason of age, or physical or mental impairment).

Presents paper or digital documentation of one of the following requirements:

(i) A negative pre-departure viral test result for SARS-CoV-2 conducted on a specimen collected no more than 1 calendar day before the flight's departure from a foreign country (Qualifying Test)

## OR

- (ii) Documentation of having recovered from COVID-19
  in the past 90 days in the form of both of the
  following (Documentation of Recovery):
  - A positive viral test result for SARS-CoV-2 conducted on a specimen collected no more than 90 calendar days before the flight; and
  - A letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel.

Each passenger must retain paper or digital documentation presented to the airline or other aircraft operator reflecting one of the following:

- A negative result for the Qualifying Test; or
- Documentation of Recovery from COVID-19.

Upon request, a passenger, or the passenger's authorized representative, must also produce such documentation to any U.S. government official or a cooperating state or local public health authority.

Pursuant to 42 CFR 71.31(b), and as set forth in greater detail below, this Notice and Amended Order constitutes a controlled free pratique to any airline or other aircraft operator with an aircraft arriving into the United States.<sup>3</sup> 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 within the United States:

- Airline or other aircraft operator must confirm that every passenger onboard the aircraft has presented a negative result for a Qualifying Test or Documentation of Recovery.
- Airline or other aircraft operator must verify that every passenger onboard the aircraft has attested to receiving a negative result for the *Qualifying Test* or having tested positive for SARS-CoV-2 on a specimen collected no more than

<sup>&</sup>lt;sup>3</sup> On October 25, 2021, the President issued a Proclamation, titled, "Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic." On November 26, 2021, the President issued a Proclamation, titled, "A Proclamation on Suspension of Entry as Immigrants and Nonimmigrants of Certain Additional Persons Who Pose a Risk of Transmitting Coronavirus Disease 2019." These Proclamations were issued pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code. This amended CDC Order complements and advances these Proclamations.

90 calendar days before the flight and been cleared to travel as Documentation of Recovery.

This Notice and Amended Order does not alter the obligation of persons to comply with the applicable requirements of other CDC Orders, including:

- Requirement for Persons to Wear Masks While on Conveyances and at Transportation Hubs (published at 86 FR 8025, February 3, 2021) (as may be further amended);
- Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic (published at 86 FR 61224, November 5, 2021); and
- Other CDC Orders or CDC Directives that may be published relating to preventing the introduction, transmission, and spread of COVID-19 into and throughout the United States.

This Notice and Amended Order supersede the previous Order signed by the CDC Director on October 25, 2021. This Order shall enter into effect for flights departing at or after 12:01 a.m. EST (5:01 a.m. GMT) on December 06, 2021.

## STATEMENT OF INTENT:

This Amended 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 the Omicron virus variant and other 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 49 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 CFR 71.1(b).

Attachment A.<sup>4</sup> Such attestation may be completed in paper or digital form. The attestation is a statement, writing, entry, or other representation under 18 U.S.C. 1001.<sup>5</sup>

Documentation of Recovery means paper or digital documentation of having recovered from COVID-19 in the form of a positive SARS-CoV-2 viral test result and a letter from a licensed healthcare provider or public health official stating that the person has been cleared for travel (i.e., has recovered). 6,7 The viral test

\_\_

<sup>&</sup>lt;sup>4</sup> CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of CDC Orders: Requirements for Negative Predeparture COVID-19 Test Result or Documentation of Recovery from COVID-19 and Testing for All Airline or Other Aircraft Passengers Arriving into the United States from Any Foreign Country and Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic.

<sup>&</sup>lt;sup>5</sup> CDC encourages airlines and aircraft operators to incorporate the attestation into paperless check-in processes. An airline or aircraft operator may use a third party (including a third-party application) to collect attestations, including to provide translations. However, an 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. An airline or aircraft operator is responsible for any failure of a third party to comply with this Order. An airline or aircraft operator may not shift any legal responsibility to a third party.

<sup>&</sup>lt;sup>6</sup> Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html</a>.

<sup>&</sup>lt;sup>7</sup> A letter from a healthcare provider or a public health official that clears the person to end isolation (e.g., to return to work or school), can also be

must have been conducted on a specimen collected no more than 90 calendar days before the departure of the flight, or at such other intervals as specified in CDC guidance.

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

Qualifying Test means a negative result on a SARS-CoV-2 viral test that was conducted on a specimen collected no more than 1 calendar day before the flight's departure from a foreign country to the United States.

United States has the same definition as "United States" in 42 CFR 71.1(b), meaning "the 50 States, District of Columbia, and the territories (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands."

Viral Test means a viral detection test for current infection (i.e., a nucleic acid amplification test [NAAT] or a viral antigen test) cleared, approved, or issued an emergency use authorization (EUA) by the U.S. Food and Drug Administration, or granted

used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

marketing authorization by the relevant national authority, for the detection of SARS-CoV-2, performed in accordance with the approval/clearance/EUA/marketing authorization.

#### EXEMPTIONS:

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

- Crew members of airlines or other aircraft operators if 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).8
- Airlines or other aircraft operators transporting passengers with COVID-19 pursuant to CDC authorization and in accordance with CDC guidance.<sup>9</sup>
- U.S. federal law enforcement personnel on official orders who are traveling for the purpose of carrying out a law

<sup>&</sup>lt;sup>8</sup> Airlines, aircraft operators, and their crew members may follow stricter protocols for crew and passenger health, including testing protocols. SAFO 20009, COVID-19: Updated Interim Occupational Health and Safety Guidance for Air Carriers and Crews, available at <a href="https://www.faa.gov/other\_visit/aviation\_industry/airline\_operators/airline\_safety/safo/all\_safos/media/2020/SAFO20009.pdf">https://www.faa.gov/other\_visit/aviation\_industry/airline\_operators/airline\_safety/safo/all\_safos/media/2020/SAFO20009.pdf</a>.

<sup>&</sup>lt;sup>9</sup> Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID-19 or COVID-19 Exposure, available at <a href="https://www.cdc.gov/quarantine/interim-guidance-transporting.html">https://www.cdc.gov/quarantine/interim-guidance-transporting.html</a>.

enforcement function, provided they are covered under an occupational health and safety program that takes measures to ensure personnel are not symptomatic or otherwise at increased risk of spreading COVID-19 during travel. Those traveling for training or other business purposes remain subject to the requirements of this Order.

- U.S. military personnel, including civilian employees, dependents, contractors, and other U.S. government employees when traveling on U.S. military assets (including whole aircraft charter operators), if such individuals are under competent military or U.S. government travel orders and observing U.S. Department of Defense guidance to prevent the transmission of COVID-19 as set forth in Force Protection Guidance Supplement 20 Department of Defense Guidance for Personnel Traveling During the Coronavirus Disease 2019 Pandemic (April 12, 2021) including its testing guidance. 10
- Individuals and organizations for which the issuance of a humanitarian exemption is necessary based on both: (1) exigent circumstances where emergency travel is required to preserve health and safety (e.g., emergency medical

<sup>10</sup> Force Protection Guidance Supplement 20 - Department of Defense Guidance
for Personnel Traveling During the Coronavirus Disease 2019 Pandemic,
available at https://media.defense.gov/2021/Apr/16/2002622876/-1/1/1/MEMORANDUM-FOR-FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT%2020DEPARTMENT-OF-DEFENSE-GUIDANCE-FOR-PERSONNEL-TRAVELING-DURING-THECORONAVIRUS-DISEASE-2019-PANDEMIC.PDF.

evacuations); and (2) where pre-departure testing cannot be accessed or completed before travel because of exigent circumstances.

#### **BACKGROUND:**

#### A. COVID-19 Pandemic

Since January 2020, the respiratory disease known as "COVID-19," caused by a novel coronavirus (SARS-CoV-2), has spread globally, including cases reported in all 50 states within the United States, plus the District of Columbia and all U.S. territories. As of December 02, 2021, there have been over 262,000,000 million cases of COVID-19 globally, resulting in over 5,200,000 deaths. In the United States, more than 48,000,000 cases have been identified, and over 775,000 deaths attributed to the disease.

SARS-CoV-2 spreads mainly from person-to-person through respiratory fluids released during exhalation, such as when an infected person coughs, sneezes, or talks. Exposure to these respiratory fluids occurs in three principal ways: (1) inhalation of very fine respiratory droplets and aerosol particles; (2)

10

<sup>11</sup> https://covid19.who.int/

deposition of respiratory droplets and particles on exposed mucous membranes in the mouth, nose, or eye by direct splashes and sprays; and (3) touching mucous membranes with hands that have been soiled either directly by virus-containing respiratory fluids or indirectly by touching surfaces with virus on them. 12,13 Spread is more likely when people are in close contact with one another (within about 6 feet), especially in crowded or poorly ventilated indoor settings. Persons who are not fully vaccinated, including those with asymptomatic or pre-symptomatic infections, significant contributors to community SARS-CoV-2 are transmission and occurrence of COVID-19.14,15

Among adults, the risk for severe illness from COVID-19 increases with age, with older adults at highest risk. 16 Severe illness

\_

<sup>12</sup> Scientific Brief: SARS-CoV-2 Transmission, Centers for Disease Control and Prevention (May 7, 2021), <a href="https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html">https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html</a>.

<sup>13</sup> Science Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community Environments, Centers for Disease Control and Prevention (Apr. 5, 2021), <a href="https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html">https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html</a>.

<sup>14</sup> Moghadas SM, Fitzpatrick MC, Sah P, et al. The implications of silent transmission for the control of COVID-19 outbreaks. Proc Natl Acad Sci U S A. 2020;117(30):17513-17515.10.1073/pnas.2008373117, available at https://www.ncbi.nlm.nih.gov/pubmed/32632012.

<sup>&</sup>lt;sup>15</sup> Johansson MA, Quandelacy TM, Kada S, et al. SARS-CoV-2 Transmission from People Without COVID-19 Symptoms. Johansson MA, et al. JAMA Netw Open. 2021 January4;4(1):e2035057. doi: 10.1001/jamanetworkopen.2020.35057.

<sup>&</sup>lt;sup>16</sup> CDC. COVID-19 Risks and Vaccine Information for Older Adults https://www.cdc.gov/aging/covid19/covid19-older-adults.html.

means that persons with COVID-19 may require hospitalization, intensive care, or a ventilator to help them breathe. People of any age with certain underlying medical conditions (e.g., cancer, obesity, serious heart conditions, diabetes, conditions that weaken the immune system) are at increased risk for severe illness from COVID-19.<sup>17</sup>

## B. Emergence of Variants of Concern: Omicron

New variants of SARS-CoV-2 have emerged globally, several of which have been broadly classified as "variants of concern." Some variants are more transmissible, even among those who are vaccinated, and some may cause more severe disease, which can lead to more hospitalizations and deaths among infected individuals. Furthermore, recent findings suggest that antibodies generated during previous infection or vaccination may have a reduced ability to neutralize some variants, resulting in reduced effectiveness of treatments or vaccines, or increased

\_

 $<sup>^{17}</sup>$  People with Certain Medical Conditions  $\frac{\text{https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html.}$ 

<sup>&</sup>lt;sup>18</sup> Dougherty K, Mannell M, Naqvi O, Matson D, Stone J. SARS-CoV-2 B.1.617.2 (Delta) Variant COVID-19 Outbreak Associated with a Gymnastics Facility — Oklahoma, April-May 2021. MMWR Morb Mortal Wkly Rep 2021;70:1004-1007. DOI: http://dx.doi.org/10.15585/mmwr.mm7028e2 (describing a B.1.617.2 (Delta) Variant COVID-19 outbreak associated with a gymnastics facility and finding that the Delta variant is highly transmissible in indoor sports settings and households, which might lead to increased incidence rates).

diagnostic detection failures.<sup>19</sup> The emergence of variants that substantially decrease the effectiveness of available vaccines against severe or deadly disease is a primary public health concern.

On November 24, 2021, the Republic of South Africa informed the World Health Organization (WHO) of a new variant of SARS-CoV-2, the virus that causes COVID-19, that was detected in that country. On November 26, 2021, WHO designated the variant B.1.1.529 as a variant of concern and named it Omicron. 20 This decision was based on the evidence presented to the Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE) which is a group of independent experts charged with assessing the evolution of SARS-CoV-2 and examining if specific mutations and combinations of mutations may alter how the virus spreads and whether it may cause more severe illness. The evidence presented to the TAG-VE noted that Omicron has several mutations that may have an impact on how easily it spreads or the severity of illness it causes. 21

\_\_\_

<sup>&</sup>lt;sup>19</sup> SARS-CoV-2 Variant Classifications and Definitions, Centers for Disease Control and Prevention, <a href="https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern">https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern</a>.

https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern

<sup>21</sup> https://www.who.int/news/item/28-11-2021-update-on-omicron

Currently, there are no data available to assess the ability of sera from vaccinated persons or those with previous SARS-CoV-2 infection to neutralize the Omicron variant. The spike protein is the primary target of vaccine-induced immunity. The Omicron variant contains more changes in the spike protein than have been observed in other variants. Based on the number of substitutions, the location of these substitutions, and data from other variants with similar spike protein substitutions, significant reductions in neutralizing activity of sera from vaccinated or previously infected individuals, which may indicate reduced protection from infection, are anticipated.<sup>22</sup>

At the present time, WHO and CDC are coordinating with many researchers around the world to better understand the Omicron variant. Studies include assessments of transmissibility, severity of infection (including symptoms), performance of vaccines and diagnostic tests, and effectiveness of treatments. CDC and other federal agencies are working closely with international public health agencies to monitor the situation closely and are taking steps to enhance surveillance for and

<sup>&</sup>lt;sup>22</sup> Science Brief: Omicron (B.1.1.529) Variant, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/scientific-brief-omicron-variant.html

response to the Omicron variant within the United States. Considering these ongoing studies into the potential danger to public health posed by this newly identified variant, CDC has determined that proactive measures must be implemented now to protect the U.S. public health from the importation, transmission and spread of the emergent Omicron variant into the United States.

C. Requirement for Pre-Departure Testing Regardless of Vaccination Status

On November 26, 2021, the President issued a Proclamation suspending the entry into the United States, of immigrants or nonimmigrants, of noncitizens who were physically present within certain Southern African countries during the 14-day period preceding their entry or attempted entry into the United States. 23 This Proclamation was issued under the authority of sections 212(f) and 215(a) of the Immigration and Nationality Act, as codified at sections 1182(f) and 1185(a) of title 8, United States Code (U.S.C.), and 3 U.S.C. section 301 based on a determination that entry of certain noncitizens covered by the

https://www.whitehouse.gov/briefing-room/presidential-actions/2021/11/26/a-proclamation-on-suspension-of-entry-as-immigrants-and-nonimmigrants-of-certain-additional-persons-who-pose-a-risk-of-transmitting-coronavirus-disease-2019/

Proclamation would be detrimental to the interests of the United States. The Proclamation directs the Secretary of State, the Secretary of Transportation, and the Secretary of Homeland Security to endeavor to ensure that any noncitizen subject to the Proclamation does not board an aircraft traveling to the United States, to the extent permitted by law. The Proclamation also states that any individuals exempt from the suspension may nevertheless be subject to an entry suspension, limitation, or restriction under Proclamation 10294 of October 25, 2021.

As virus that causes COVID-19 spreads, it has opportunities to change (mutate) and become more difficult to control. While it is known and expected that viruses change through mutation leading to the emergence of new variants, the emergent Omicron variant is particularly concerning and of critical significance for this Amended Order. CDC has determined that given the rapid spread of the Omicron variant, including to countries and regions outside of those originally identified in the November 26 Proclamation, requiring a SARS-CoV-2 test no more than 1 calendar day before the flight's departure from a foreign country as specified in this Notice and Amended Order, and applicable to all passengers regardless of vaccination status or country of origin (except passengers who present valid Documentation of Recovery), is necessary to protect the public health of the United States.

In response to this new variant, the United States Government, including CDC, reexamined its policies on international travel and concluded the proactive 1 calendar day testing measure is necessary to protect the public health and should remain in place until more information becomes available that may alter or improve the public health outlook. This Amended Order requires that all passengers, regardless of vaccination status or country of origin, except passengers who present a valid Documentation of Recovery, provide documentation of a negative SARS-CoV-2 viral test result from a specimen collected no more than 1 calendar day preceding the departure of the passenger's originating flight to the United States. While CDC's previous Amended Order<sup>24</sup> indicated that "decreasing the time window for testing before departure from three days to one day provides minimal additional public health benefit for fully vaccinated travelers," this statement did not account for the Omicron variant, which had not yet been identified.

At this time, it is unknown what level of protection current

\_

https://www.federalregister.gov/documents/2021/11/05/2021-24388/requirement-for-negative-pre-departure-covid-19-test-result-or-documentation-of-recovery-from

vaccines will provide against this newly emergent mutated variant. To best protect the health of the United States, unless and until CDC can confirm that current approved and authorized vaccines provide adequate protection against the Omicron variant, all passengers - including those who are fully vaccinated, but excluding passengers who present a valid Documentation of Recovery - must obtain a viral test on a specimen collected no more than 1 calendar day before their flight's departure to meet the requirements of this Amended Order. The one-day time window, a reduction from the previous 3-day window for fully vaccinated passengers, will provide less opportunity to develop infection with the Omicron variant prior to arrival into the United States.

Testing for SARS-CoV-2 infection is a proactive, risk-based approach that is not dependent on the infecting variant, nor on vaccination status of the individual. This risk-based testing approach 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. 25 Most countries now use testing in some form to monitor risk and

\_

<sup>&</sup>lt;sup>25</sup> Runway to Recovery 1.1, December 21, 2020, available at https://www.transportation.gov/briefing-room/runway-recovery-11.

control introduction and spread of SARS-CoV-2.26 With case counts and deaths due to COVID-19 continuing to increase around the globe and the emergence of the new and concerning Omicron variant, the United States is taking a multi-layered proactive approach to combating COVID-19, concurrently preventing and slowing the continued introduction of cases and further spread of the virus within U.S. communities. CDC acknowledges that pre-departure testing does not eliminate all risk.

D. Statement of Good Cause under the Administrative Procedure Act ("APA")

To reduce introduction and spread of current and future SARS-CoV-2 variants into the United States at a time when global air travel is increasing, CDC must take quick and targeted action to help curtail the introduction and spread of the Omicron variant into the United States. As of December 2, 2021, WHO has indicated that 23 countries have reported cases of the Omicron variant, many of which were associated with international travelers.

This Amended Order is not a rule within the meaning of the

<sup>26</sup> https://ourworldindata.org/coronavirus-testing#testing-and-contact-tracingpolicy

Administrative Procedure Act ("APA") but rather is an emergency action taken under the existing authority of 42 U.S.C. 264(a) and 42 CFR 71.20 and 71.31(b), which were promulgated in accordance with the APA after full notice-and-comment rulemaking and a delay in effective date. In the event that this Amended Order qualifies as a new rule under the APA, notice and comment and a delay in effective date are not required because there is good cause to dispense with prior public notice and comment and a delay in effective date. See 5 U.S.C. 553(b)(B), (d)(3).

Considering the rapid and unpredictable developments in the public health emergency caused by COVID-19, including the recently identified emergent Omicron variant, it would be impracticable and contrary to the public's health, and by extension the public's interest, to delay the issuance and effective date of this Amended Order. Further delay could increase risk of transmission and importation of additional undetected cases of SARS-CoV-2 Omicron variant or other emerging variants through passengers.

Similarly, the Office of Information and Regulatory Affairs has determined that if this Amended Order were a rule, it would be a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act),

5 U.S.C. 804(2), but there would not be a delay in its effective date as the agency has determined that there would be good cause to make the requirements herein effective immediately under the APA, 5 U.S.C. 808(2).

This Amended Order is also an economically significant regulatory action under Executive Order 12866 and has therefore been reviewed by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

If any provision of this Amended Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, the remainder of the provisions, or the application of such provisions to any carriers, persons, or circumstances other than those to which it is held invalid, shall remain valid and in effect.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that notice-and-comment rulemaking would defeat the purpose of the Amended Order and endanger the public health, and is, therefore, impracticable and contrary to the public interest. For the same reasons, I have determined, consistent with 5 U.S.C. 553(d)(3), that there is good cause to make this Amended

Order effective immediately upon filing at the Office of the Federal Register.

## ACTION:

For the reasons outlined above, I hereby determine that passengers covered by this Amended Order are at risk of transmitting SARS-CoV-2 virus, including the emergent Omicron variant and other virus variants. Accordingly, requiring passengers to demonstrate predeparture either a negative COVID-19 test result or recovery from COVID-19 after previous SARS-CoV-2 infection in the past 90 days is necessary to reduce the risk of transmission of the SARS-CoV-2 virus, including the Omicron variant and other virus variants, and to protect the health of fellow passengers, aircraft crew, and U.S. communities. This Amended Order shall remain effective until either the expiration of the Secretary of HHS' declaration that COVID-19 constitutes a public health emergency, or I determine that based on specific public health or other considerations that continuation of this Order is no longer necessary to prevent the further introduction, transmission, and spread of COVID-19 into the United States, whichever occurs first. Upon determining that continuation of this Order is no longer necessary to prevent the further introduction, transmission, and spread of COVID-19 into the United States, I will publish a notice in the Federal Register terminating this Order. I retain the authority to modify or terminate the Order, or its implementation, at any time as needed to protect public health.

# 1. Requirements for Airlines & Other Aircraft Operators

Any airline or other aircraft operator with passengers arriving into the United States from a foreign country, shall:

- A. Confirm that every passenger 2 years or older onboard the aircraft has paper or digital documentation reflecting a Qualifying Test or Documentation of Recovery.
  - 1) Requirements for a Qualifying Test include:
    - a. Documentation of a negative SARS-CoV-2 viral test result from a specimen collected no more than 1 calendar day preceding the passenger's flight to the United States.

      The negative SARS-CoV-2 viral test result must include:
      - i. personal identifiers (e.g., name and date of birth) on the negative test result that match the personal identifiers on the passenger's passport or other travel documents;
      - ii. a specimen collection date indicating that the specimen was collected no more than 1 calendar

- day before the flight's departure (or first flight in a series of connections booked on the same itinerary);
- iii. the type of viral test indicating it is a NAAT
   or antigen test;
  - iv. a test result that states "NEGATIVE," "SARS-COV-2 RNA NOT DETECTED," "SARS-COV-2 ANTIGEN NOT DETECTED," or "COVID-19 NOT DETECTED," or other indication that SARS-CoV-2 was not detected in the individual's specimen. A test marked "invalid" is not acceptable; and
    - v. information about the entity issuing the result (e.g., laboratory, healthcare entity, or telehealth service), such as the name and contact information.
- 2) Requirements for Documentation of Recovery include:
  - a. documentation of a positive SARS-CoV-2 viral test result from a specimen collected no more than 90 calendar days preceding the passenger's scheduled

flight to the United States.<sup>27</sup> The positive SARS-CoV-2 viral test result must include:

- i. personal identifiers (e.g., name and date of birth) on the positive test result match the personal identifiers on the passenger's passport or other travel documents;
- ii. a specimen collection date indicating that the
   specimen was collected no more than 90 calendar
   days before the flight's departure;
- iii. information that the test performed was a viral
   test indicating it is a NAAT or antigen test;
  - iv. a test result that states "POSITIVE," "SARS-CoV2 RNA DETECTED," "SARS-CoV-2 ANTIGEN DETECTED,"
     or "COVID-19 DETECTED," or other indication that
     SARS-CoV-2 was detected in the individual's
     specimen. A test marked "invalid" is not
     acceptable; and
  - v. information about the entity issuing the result (e.g., laboratory, healthcare entity, or telehealth service), such as the name and contact information.

<sup>&</sup>lt;sup>27</sup> Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

- b. A signed letter from a licensed healthcare provider or a public health official stating that the passenger has been cleared for travel. 28,29 The letter must have personal identifiers (e.g., name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents. The letter must be signed and dated on official letterhead that contains the name, address, and phone number of the healthcare provider or public health official who signed the letter.
- B. Confirm that each passenger has attested to having received a negative result for a *Qualifying Test* or having tested positive for SARS-CoV-2 on a specimen collected no more than 90 calendar days before the flight and been cleared 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**.

<sup>&</sup>lt;sup>28</sup> Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html</a>.

<sup>&</sup>lt;sup>29</sup> A letter from a healthcare provider or a public health official that clears the person to end isolation, e.g., to return to work or school, can also be used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

C. Not board any passenger without confirming the documentation as set forth in section 1.A and 1.B.

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

# 2. Requirements for Aircraft Passengers

Any aircraft passenger  $^{30}$  departing from any foreign country with a destination in the United States shall -

- A. Present paper or digital documentation reflecting one of the following:
  - 1) A negative Qualifying Test that has a specimen collection date indicating that the specimen was collected no more than 1 calendar day before the flight's departure (or first flight in a series of connections booked on the same itinerary); or

<sup>&</sup>lt;sup>30</sup> A parent or other authorized individual may present the required documentation on behalf of a passenger 2-17 years of age. An authorized individual may act on behalf of any passenger who is unable to act on their own behalf (e.g., by reason of age, or physical or mental impairment).

- 2) Documentation of Recovery from COVID-19 that includes a positive SARS-CoV-2 viral test result conducted on a specimen collected no more than 90 calendar days before the flight and a letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel. 31,32
- B. Provide the attestation to the airline or other aircraft operator, of:
  - 1) having received a negative result for the Qualifying
     Test; or
  - 2) having tested positive for SARS-CoV-2 on a specimen collected no more than 90 calendar days before the flight and been cleared to travel.

The attestation is attached to this order as **Attachment A**. Unless otherwise permitted by law, a parent or other authorized individual may present the required documentation on behalf of a passenger 2-17 years of age. An authorized individual may act on behalf of any passenger who is unable

<sup>&</sup>lt;sup>31</sup> A letter from a healthcare provider or a public health official that clears the person to end isolation, e.g., to return to work or school, can also be used to show that the person has been cleared to travel, even if travel is not specifically mentioned in the letter.

<sup>32</sup> Healthcare providers and public health officials should follow CDC guidance in clearing patients for travel to the United States. Applicable guidance is available at <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html</a>.

to act on their own behalf (e.g., by reason of age, or physical or mental impairment).

C. Retain a copy of the applicable documentation listed in part

A of this section and produce such documentation upon request
to any U.S. government official or a cooperating state or
local public health authority after arrival into the United
States.

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 CFR 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.

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

As the pandemic continues to rapidly evolve and more scientific data becomes available regarding the emergent Omicron variant and/or the effectiveness of COVID-19 vaccines related to currently circulating variants, CDC may exercise its enforcement discretion to adjust the scope of accepted pre-departure testing requirements to allow passengers and airline and aircraft operators greater

flexibility regarding the requirements of this Amended Order or to align with current CDC guidance. Such exercises of enforcement discretion will be announced on CDC's website and the Amended Order will be further amended as soon as practicable through an updated publication in the Federal Register.

## EFFECTIVE DATE:

This Amended Order shall enter into effect for flights departing at or after 12:01 a.m. EST (5:01 a.m. GMT) on December 6, 2021, and will remain in effect unless modified or rescinded based on specific public health or other considerations, or until the Secretary of Health and Human Services rescinds the determination under section 319 of the Public Health Service Act (42 U.S.C. 247d) that a public health emergency exists with respect to COVID-19.

In testimony whereof, the Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, has hereunto set her hand at Atlanta, GA, this December 02, 2021.

Hostally Pla soomen

Rochelle P. Walensky, MD, MPH

Director, Centers for Disease Control and Prevention