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)

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

SUMMARY:

Pursuant to 42 CFR 71.20, 71.31(b) and as set forth in greater detail below, this Notice and Amended Order¹ prohibits the boarding of any passenger – 2 years of age or older - on any aircraft destined to the United States² from a foreign country unless the passenger³ presents:

- (1) Paper or digital documentation of a negative pre-departure viral test result for SARS-CoV-2, the virus that causes COVID-19, that meets one of the following requirements:
 - For passengers who are fully vaccinated against COVID-19, the viral test must be conducted on a specimen collected no more than 3 calendar days before the flight's departure from a foreign country (*Qualifying Test for Fully Vaccinated*).
 - For passengers who are not fully vaccinated against COVID-19, the viral test must be conducted on a specimen collected no more than 1 calendar day before the flight's departure from a foreign country (*Qualifying Test for Not Fully Vaccinated*).

<u>Or</u>

(2) Paper or digital documentation of recovery from COVID-19 in the form of both:

- A positive 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 (*Documentation of Recovery*).

¹ This Amended Order supersedes the previous order signed by the Centers for Disease Control and Prevention (CDC) Director on January 25, 2021.

² This includes any flight, regardless of whether the United States is final destination or connection to another country.

³ 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).

The option to present *Documentation of Recovery* is available to passengers regardless of their vaccination status.

Passengers who have a *Qualifying Test for Fully Vaccinated*, i.e., a negative pre-departure viral test conducted on a specimen collected no more than **3 calendar days** before the flight's departure from a foreign country, must have paper or digital documentation of being fully vaccinated with an *Accepted COVID-19 Vaccine* (*Proof of Being Fully Vaccinated Against COVID-19*).

Passengers who have a *Qualifying Test for Not Fully Vaccinated*, i.e., a negative pre-departure viral test conducted on a specimen collected no more than **1 calendar day** before the flight's departure from a foreign country, do not need to present *Proof of Being Fully Vaccinated Against COVID-19*.

Alternatively, if a passenger has tested positive for SARS-CoV-2 on a specimen collected no more than 90 calendar days before the flight's departure and recovered from COVID-19 (i.e., met CDC criteria to end isolation),⁴ the passenger may instead travel with paper or digital documentation of the positive viral test result that confirms the previous SARS-CoV-2 infection and a letter from a licensed healthcare provider or public health official stating that the passenger has been cleared for travel (*Documentation of Recovery*).

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

- Negative result for *Qualifying Test for Fully Vaccinated* plus *Proof of Being Fully Vaccinated Against COVID-19*;
- Negative result for the Qualifying Test for Not Fully Vaccinated; or
- *Documentation of Recovery* from COVID-19.

A passenger, or the passenger's authorized representative, must also produce such documentation upon request 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 constitute a controlled free pratique to any airline or other aircraft operator with an aircraft arriving in the United States.⁵ 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:

⁴ https://www.cdc.gov/coronavirus/2019-ncov/your-health/quarantine-isolation.html.

⁵ On October 25, 2021, the President issued a Proclamation pursuant to Sections 1182(f) and 1185(a)(1) of Title 8, and Section 301 of Title 3, United States Code, titled, "Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic." Pursuant to this Proclamation. The President has implemented a global suspension and restriction on entry for noncitizens who are nonimmigrants seeking to enter the United States by air travel and who are not fully vaccinated against COVID-19. This amended CDC Order complements and advances the safe resumption of global travel.

- Airline or other aircraft operator must confirm that every passenger onboard the aircraft based on vaccination status **has documentation** of a negative result for a *Qualifying Test for Fully Vaccinated* plus *Proof of Being Fully Vaccinated Against COVID-19*, a negative result for a *Qualifying Test for Not Fully Vaccinated*, or *Documentation of Recovery*.
- Airline or other aircraft operator must verify that every passenger onboard the aircraft based on vaccination status **has attested** to receiving a negative result for the *Qualifying Test for Fully Vaccinated* plus being fully vaccinated, receiving a negative result for the *Qualifying Test for Not Fully Vaccinated*, 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 as *Documentation of Recovery*. 6

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:

Accepted COVID-19 Vaccine means:

- A vaccine authorized for emergency use or approved by the U.S. Food and Drug Administration;⁷ or
- A vaccine listed for emergency use by the World Health Organization (WHO);8 or
- A vaccine or combination of vaccines⁹ listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order.

⁶ 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).

⁷ For a list of vaccines approved or authorized in the United States to prevent COVID-19, see https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html

⁸ See WHO's website for more information about WHO emergency use-listed COVID-19 vaccines.

⁹ CDC has not recommended the use of heterologous (i.e., mix-and-match) primary series. However, the use of such strategies (including mixing of mRNA, adenoviral, and mRNA plus adenoviral products) is increasingly common in

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).

Attest/Attestation means having completed the attestation in **Attachment A.**¹⁰ 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. 1001.¹¹

Documentation of Recovery means paper or digital documentation of recovery 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). ^{12,13} The viral test must have been conducted on a specimen collected no more than 90 calendar days before the departure of the flight.

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

Fully Vaccinated Against COVID-19 means it has been:

many countries outside of the United States. Accordingly, additional vaccinations or combinations of vaccinations may be listed in CDC's in Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order for purposes of the interpretation of vaccination records.

¹⁰ CDC has provided a combined passenger disclosure and attestation that fulfills the requirements of CDC Orders: Requirement for Proof of Negative COVID-19 Test Result or Recovery from COVID-19 for All Airline Passengers Arriving into the United States and Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic.

¹¹ 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.

¹² Healthcare 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.

¹³ 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.

- 2 weeks (14 days) or more since a person received one dose of an accepted single-dose series COVID-19 vaccine; OR
- 2 weeks (14 days) or more since a person's second dose in a 2-dose series of an accepted COVID-19 vaccine; OR
- 2 weeks (14 days) or more since a person received a complete series of a vaccine or combination of vaccines listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order.

Not Fully Vaccinated Against COVID-19 means a person does not meet the definition of Fully Vaccinated Against COVID-19.

Proof of Being Fully Vaccinated against COVID-19 means a person has an acceptable paper or digital format of a vaccination record or a verifiable vaccination record confirming that the person is Fully Vaccinated Against COVID-19 as defined and listed by CDC in CDC's Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order.

Qualifying Test for Fully Vaccinated means a negative result on a SARS-CoV-2 viral test that was conducted on a specimen collected no more than 3 calendar days before the flight's departure from a foreign country to the United States for passengers who have Proof of Being Fully Vaccinated Against COVID-19.

Qualifying Test for Not Fully Vaccinated 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 for passengers who do not have Proof of Being Fully Vaccinated Against COVID-19.

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) approved or authorized by the relevant national authority or the U.S. Food and Drug Administration for the detection of SARS-CoV-2.

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).¹⁴
- Airlines or other aircraft operators transporting passengers with COVID-19 pursuant to CDC authorization and in accordance with CDC guidance. ¹⁵
- U.S. federal law enforcement personnel on official orders who are traveling for the
 purpose of carrying out a law 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. 16
- 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 evacuations) and 2) where predeparture testing cannot be accessed or completed before travel because of exigent circumstances. Additional conditions may be placed on those granted such exemptions, including but not limited to, observing precautions during travel, providing consent to post-arrival testing, and/or self-quarantine after arrival in the United States, as may be directed by federal, state, territorial, tribal or local public health authorities to reduce the risk of transmission.

BACKGROUND:

¹⁴ 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

 $\underline{https://www.faa.gov/other_visit/aviation_industry/airline_operators/airline_safety/safo/all_safos/media/2020/SAFO_20009.pdf.$

¹⁵ 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 https://www.cdc.gov/quarantine/interim-guidance-transporting.html.

¹⁶ 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/-1/1/MEMORANDUM-FOR-FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT%2020-DEPARTMENT-OF-DEFENSE-GUIDANCE-FOR-PERSONNEL-TRAVELING-DURING-THE-CORONAVIRUS-DISEASE-2019-PANDEMIC.PDF.

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 October 22, 2021, there have been over 242,000,000 million cases of COVID-19 globally, resulting in over 4,900,000deaths. More than 45,000,000 cases have been identified in the United States, with new cases reported daily, and over 733,000 deaths have been attributed to the disease. A renewed surge in cases in the United States began in early July 2021; daily case counts rose from 19,000 cases on July 1, 2021 to 159,000 cases on September 1, 2021. While cases are currently decreasing in the United States, during the entirety of this pandemic, cases have tended to surge in waves, including after high-volume travel periods, with 4 waves as of October 2021. Therefore, additional surges of cases and deaths are very possible.

Many countries have begun widespread vaccine administration; however, 98 countries continue to experience high or substantial incidence rates (>50 cases per 100,000 people in the last seven days) and 65 countries, including the United States, are experiencing a high incidence of reported new cases at this time. ¹⁹

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) 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. ^{20,21} 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, are significant contributors to

¹⁷ https://covid19.who.int/

¹⁸ https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

¹⁹ https://covid19.who.int/

²⁰ Scientific Brief: SARS-CoV-2 Transmission, Centers for Disease Control and Prevention (May 7, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html.

²¹ Science Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community Environments, Centers for Disease Control and Prevention (Apr. 5, 2021), https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html.

community SARS-CoV-2 transmission and occurrence of COVID-19.^{22,23}

Among adults, the risk for severe illness from COVID-19 increases with age, with older adults at highest risk.²⁴ Severe illness means that persons with COVID-19 may require hospitalization, intensive care, or a ventilator to help them breathe, and may die. 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-19.²⁵

B. Emergence of Variants of Concern

New variants of SARS-CoV-2 have emerged globally, several of which have been identified as variants of concern, including the Delta variant. Some variants are more transmissible and some may cause more severe disease, which can lead to more hospitalizations, and deaths among infected individuals. Furthermore, findings suggest some variants may reduce levels of virus neutralization by antibodies generated during previous infection or vaccination, resulting in reduced effectiveness of treatments or vaccines, or increased diagnostic detection failures. The emergence of variants that substantially decreases the effectiveness of available vaccines against severe or deadly disease is a primary public health concern. While such a variant of high consequence has not yet been identified, so long as new variants of SARS-CoV-2 continue to emerge and circulate, the potential for such a variant remains not only a possibility, but a current reality.

As the virus spreads, it has new opportunities to change (mutate) and may become more difficult to control. While it is known and expected that viruses change through mutation leading to the emergence of new variants, the existing Delta variant is particularly concerning

²² 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.

²³ 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.

²⁴ CDC. COVID-19 Risks and Vaccine Information for Older Adults https://www.cdc.gov/aging/covid19/covid19-older-adults.html.

²⁵ People with Certain Medical Conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

²⁶ 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).

²⁷ SARS-CoV-2 Variant Classifications and Definitions, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern.

because it spreads more easily than previous variants of SARS-CoV-2. ²⁸ The Delta variant has rapidly become the predominant strain in the United States with more than 99% of U.S. cases attributed to it as of October 16, 2021. ²⁹ Globally, 193 countries have reported cases of the Delta variant as of October 19, 2021. ³⁰

Of critical significance for this Amended Order, the Delta variant has increased transmissibility, especially among persons who are not fully vaccinated, and increases the risk of infection in fully vaccinated individuals in the absence of other mitigation strategies, such as mask wearing. For persons not fully vaccinated, Delta is a formidable threat and the surge in cases since the summer of 2021 has been fueled in part by low vaccination coverage in many U.S. communities. Available evidence suggests all three vaccines currently approved or authorized in the United States provide significant protection. However, a small proportion of people who are fully vaccinated may become infected, a risk that is increased with the Delta variant; emerging evidence suggests that fully vaccinated persons who do become infected with the Delta variant are at risk for transmitting it to others. However, the vast majority of fully vaccinated individuals continue to be protected from severe illness, hospitalization, and death, even with the Delta variant.

C. Availability of Testing and Vaccines in the United States and Globally

The potential for asymptomatic and pre-symptomatic transmission makes testing an essential part of COVID-19 mitigation protocols. With the additional testing capacity available through antigen tests, infected persons can be identified more rapidly so they can be isolated until they no longer pose a risk of spreading the virus and their close contacts can be identified and

²⁸ Li B, Deng A, Li K, et al. Viral Infection and Transmission in a Large Well-Traced Outbreak Caused by the Delta SARS-CoV-2 Variant. medRxiv. 2021 Jul 12; https://doi.org/10.1101/2021.07.07.21260122.

²⁹ https://covid.cdc.gov/covid-data-tracker/#variant-proportions

³⁰ https://www.who.int/publications/m/item/weekly-epidemiological-update-on-covid-19---19-october-2021.

³¹ Delta Variant: What We Know About the Science, https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html .

³² COVID Data Tracker Weekly Review, Interpretive Summary for July 23, 2021, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07232021.htmlhttps://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/past-reports/07232021.html.

³³ Science Brief: COVID-19 Vaccines and Vaccination, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html. Other vaccines, particularly the one manufactured by AstraZeneca, show reduced efficacy against infection with certain variants but may still protect against severe disease; at the time of the issuance of this Order, the FDA has not authorized the AstraZeneca COVID-19 vaccine for use in the United States.

³⁴ Delta Variant: What We Know About the Science, https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html

quarantined.³⁵

COVID-19 vaccines are now widely available in the United States, and vaccination is recommended for all people 12 years of age and older. As of October 23, 2021, approximately 190.4 million people in the United States (67.1% of the population 12 years or older) have been fully vaccinated and over 219 million people in the United States (77.6% of the population 12 years or older) have received at least one dose. ³⁶ However, after a rapid increase in the proportion of the U.S. population vaccinated against COVID-19 in the first months of 2021, vaccinations administered in the United States have slowed, particularly in those under the age of 65 years. ³⁷

The combination of the substantial proportion of the population that remains not fully vaccinated either through ineligibility (in the case of children under 12 years) or by choice, and the extreme transmissibility of the Delta variant resulted in sharp increases in COVID-19 cases in the United States over the summer and early fall of 2021, primarily and disproportionately affecting persons not fully vaccinated.

The availability of COVID-19 vaccines is also rising globally but is still small when compared to the availability of vaccines in the United States and a handful of other countries.³⁸ Approximately 6.84 billion doses of COVID-19 vaccine have been administered globally. However, vaccine supplies and testing capacity remain limited in many low-income countries.^{39,40} Outbreaks linked to international travel caused by unvaccinated and untested travelers have the potential to increase the introduction, transmission, and spread of COVID-19 variants into the United States. Many other countries around the world are making efforts to

³⁵ See COVID-19 Testing and Diagnostics Working Group (TDWG). U.S. Department of Health and Human Services (HHS), https://www.hhs.gov/coronavirus/testing-testing-diagnostics-working-group/index.html. (defining the role of the COVID-19 TDWG, which develops testing-related guidance and provides targeted investments to expand the available testing supply and maximize testing capacity).

³⁶ https://covid.cdc.gov/covid-data-tracker/#vaccinations vacc-total-admin-rate-total.

³⁷ Ibid.

³⁸ See "PAHO Director calls for fair and broad access to COVID-19 vaccines for Latin America and the Caribbean," Pan American Health Organization, https://www.paho.org/en/news/7-7-2021-paho-director-calls-fair-and-broad-access-covid-19-vaccines-latin-america-and (noting the discrepancies in vaccine availability coverage among North, Central, and South American countries).

³⁹ https://ourworldindata.org/covid-vaccinations.

⁴⁰ https://ourworldindata.org/coronavirus-testing#testing-vs-gdp-per-capita

increase COVID-19 vaccination for their populations, with some considering or adding proof of vaccination requirements as a condition for entry. 41,42, 43

CDC is aware of a rising number of SARS-CoV-2 infections in vaccinated individuals; ⁴⁴ since vaccines are not 100% effective at preventing infection, some people who are fully vaccinated may still get COVID-19. While the vaccines currently approved or authorized by the FDA are successful in preventing severe illness and death, including from the highly transmissible Delta variant, infections and even mild to moderate illness have been documented in a small percentage of vaccinated persons. However, studies so far show that vaccinated people are 5 times less likely to be infected and more than 10 times less likely to experience hospitalization or death due to COVID-19 than people who are not fully vaccinated. ⁴⁵ The emergence of the more transmissible Delta variant, as well as the potential emergence of a variant of high consequence that could reduce the effectiveness of treatments or vaccines, increases the urgency to expand vaccination coverage.

D. Justification for Continued Pre-Departure Testing

On December 25, 2020, in response to a new COVID-19 variant (now referred to as the Alpha variant⁴⁶) spreading in the United Kingdom (UK), CDC issued an Order requiring proof of a negative viral test result for all air passengers 2 years of age and older arriving from the UK to the United States. A month later, cases, including those from the Alpha variant, continued to increase significantly, and variants of concern were identified in other countries, leading to CDC issuing an Order on January 25, 2021 requiring all air passengers 2 years of age and older traveling from any foreign country to show a negative pre-departure COVID-19 test result or documentation of recovery from COVID-19 in the previous 90 calendar days before boarding a flight to the United States.

Testing for SARS-CoV-2 infection is a proactive, risk-based approach that is not dependent on the infecting variant. This risk-based testing approach has been addressed in CDC guidance

⁴¹ See CNN Travel, New Zealand says foreign nationals must have coronavirus vaccination to enter country from November, https://www.cnn.com/travel/article/new-zealand-travel-vaccination-covid-lockdown-ardern-intl/index.html.

⁴² See CNN Canada issues COVID-19 vaccine mandate for travelers 12 or older on trains and planes, https://www.cnn.com/travel/article/canada-trudeau-vaccine-mandate/index.html

 $[\]frac{43}{https://www.forbes.com/sites/geoffwhitmore/2021/10/20/covid-19-vaccine-mandates-fortravel/?sh=23fc0cdd4edb$

⁴⁴ COVID-19 Vaccine Breakthrough Case Investigation and Reporting, https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html.

⁴⁵ Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status - 13 U.S. Jurisdictions, April 4-July 17, 2021. MMWR Morb Mortal Wkly Rep. 2021;70(37):1284-1290. Published 2021 Sep 17. doi:10.15585/mmwr.mm7037e1

⁴⁶ SARS-CoV-2 Variant Classifications and Definitions, https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html.

and the Runway to Recovery guidance jointly issued by the Departments of Transportation, Homeland Security, and Health and Human Services. 47 Most countries now use testing in some form to monitor risk and control introduction and spread of SARS-CoV-2. 48 With case counts and deaths due to COVID-19, particularly the Delta variant, continuing to increase around the globe, the high proportion of unvaccinated people in the United States and around the world, and infected people with asymptomatic or pre-symptomatic infections, the United States is taking a multi-layered approach to combatting COVID-19, concurrently preventing and slowing the continued introduction of cases and further spread of the virus within U.S. communities. Vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission during travel and in avoiding severe illness, hospitalization, and death; however, infections in fully vaccinated people indicate that vaccination is a necessary but not sufficient measure; testing of these travelers is still necessary and thus required.

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, physical distancing, and hand hygiene, it can make travel safer by reducing spread on conveyances, in transportation hubs, and at destinations. CDC recommends all international travelers get a viral test 3-5 days after arrival at their U.S. destination, combined with self-monitoring. Additionally, CDC recommends international travelers who are not fully vaccinated stay home (or in a comparable location such as a hotel room) and self-quarantine for a full 7 days after travel, or for 10 days if they do not get tested, to further reduce the risk of translocating the virus into destination communities.⁴⁹

People who have recovered from COVID-19 can continue to shed detectable but non-infectious SARS-CoV-2 RNA in upper respiratory specimens for up to 3 months after illness onset. ⁵⁰ For this reason, CDC does not recommend retesting of persons previously diagnosed with COVID-19 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, unless they have symptoms of COVID-19. People who develop any symptoms of COVID-19 during this 90-day period following infection should not travel and should consult a healthcare provider who can evaluate for other causes of their symptoms and determine if testing is needed. This guidance may be updated as additional information about people who have recovered from COVID-19 becomes available.

E. Pre-Departure Testing Requirements Based on Vaccination Status

⁴⁷ Runway to Recovery 1.1, December 21, 2020, available at https://www.transportation.gov/briefing-room/runway-recovery-11.

⁴⁸ https://ourworldindata.org/coronavirus-testing#testing-and-contact-tracing-policy

⁴⁹ International Travel During COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html.

⁵⁰ https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

Recent CDC modeling that incorporated the transmission characteristics of the Delta variant shows evidence that for persons not fully vaccinated, getting a viral test one day prior to departure can reduce the risk of traveling with COVID-19 by 40%. ⁵¹ When this window is expanded to two days prior to departure, the reduction in risk is 26%, and for three days prior to departure, the risk reduction is only an estimated 14%. This modeling was based on real-world data on virus transmissibility. ^{52,53,54}

CDC's modeling also demonstrates that among travelers who are fully vaccinated with a vaccine that has 60% effectiveness against SARS-CoV-2 infection, getting tested with a NAAT or antigen test 3 days before departure can reduce risk that a person is infectious with COVID-19 during travel by 66%. Among fully vaccinated travelers, if this testing window is decreased to two days, this risk is reduced by 71%, and by 76% at one day before travel. Therefore, there is little public health advantage to shortening the time period for testing for fully vaccinated air passengers. The combination of vaccination and pre-travel testing provides a greater level of protection than either measure alone and is consistent with a layered strategy.

These models informed by analyses of real-world surveillance data support the requirement of this Amended Order that passengers who are not fully vaccinated get a specimen collected for a viral COVID-19 test no more than 1 day before departure to the United States to minimize the risk of transmission during travel and importing additional COVID-19 cases and possible variants into the United States. The time window between testing and travel is particularly relevant for those with longer-duration travel, such as traveling long distances or on connecting flights. However, decreasing the time window for testing before departure from three days to one day provides minimal additional public health benefit for fully vaccinated travelers. Therefore, fully vaccinated air passengers will continue to be allowed to get a specimen collected no more than 3 calendar days before their flight departure to meet the requirements of this Amended

⁵¹ Public Health Guidance for Potential COVID-19 Exposure Associated with Travel https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html.

⁵² He, X., Lau, E.H.Y., Wu, P. et al. Temporal dynamics in viral shedding and transmissibility of COVID-19. Nat Med 26, 672–675 (2020). https://doi.org/10.1038/s41591-020-0869-5.

⁵³ Wölfel, R., Corman, V.M., Guggemos, W. et al. Virological assessment of hospitalized patients with COVID-2019. Nature 581, 465–469 (2020). https://doi.org/10.1038/s41586-020-2196-x.

⁵⁴ Rachael Pung, Tze Minn Mak, Adam J Kucharski, Vernon J Lee, Serial intervals in SARS-CoV-2 B.1.617.2 variant cases, The Lancet, 2021 ISSN 0140-6736, https://doi.org/10.1016/S0140-6736(21)01697-4.

⁵⁵ Public Health Guidance for Potential COVID-19 Exposure Associated with Travel https://www.cdc.gov/coronavirus/2019-ncov/php/risk-assessment.html.

⁵⁶ CDC recommends that fully vaccinated cruise ship passengers receive a COVID-19 PCR or rapid antigen test no more than 2 days before boarding or on embarkation day. See https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html. While cruise ships share similarities with other forms of travel, including air travel, cruise ships represent a unique environment that facilitates the spread of COVID-19 based on such factors as their larger size, with larger cruises of more than 6,000 passengers, and ability to bring an international cohort of passengers and crew together for days or weeks at a time through frequent events such as group and buffet dining, entertainment events, and excursions. Accordingly, testing, and other public health recommendations for cruise ships and air travel may differ.

Order.

F. Proof of Being Fully Vaccinated Against COVID-19

Documentation of COVID-19 vaccination status varies globally. Governments, private industries, or medical providers may use a paper or digital certification reflecting a person's COVID-19 vaccination status that includes handwritten or typed text from an authorized healthcare care provider, pharmacy, or other qualified entity. Some governments and private industries have developed vaccination credentials that are considered "verifiable" because they can be electronically linked back to a person's vaccination data held by a trusted source. The trusted source is able to then confirm the authenticity and validity of the certificate and/or confirm that the vaccination took place. An example of verifiable vaccination credentials is a QR code image on paper or in digital format, such as on a mobile phone, that links to the person's verified vaccination data.

Considering the variability of vaccine credentials globally, this Amended Order provides the airline or aircraft operator the discretion to accept different forms of vaccine credentials, whether paper, digital, or verifiable, for passengers who submit a *Qualifying Test for Fully Vaccinated* accompanied by *Proof of Being Fully Vaccinated Against COVID-19*. While this Amended Order may be enforced through criminal penalties under 18 U.S.C. 3559, 3571; 42 U.S.C. 271; and 42 CFR 71.2, CDC does not intend to rely on this enforcement mechanism for airlines or aircraft operators who accept paper or digital documentation of vaccination (i.e., paper or digital vaccination records, verifiable vaccination credential) from a passenger in good faith and use best efforts to fulfill the requirements of this Amended Order.

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

COVID-19 cases, hospitalizations, and deaths rapidly increased over the summer and early fall of 2021, especially in areas with higher levels of community transmission and lower vaccination coverage. ⁵⁷ Pediatric cases and hospitalizations also increased over the same time period. ^{58,59} While cases are currently decreasing in the United States, during the entirety of this pandemic, cases have tended to surge in waves, including after high-volume travel periods, with 4 waves as of October 2021. ¹⁸ Therefore, additional surges of cases and deaths are very possible.

⁵⁷ Scobie HM, Johnson AG, Suthar AB, Severson R, Alden NB, Balter S, Bertolino D, Blythe D, Brady S, Cadwell B, Cheng I. Monitoring incidence of covid-19 cases, hospitalizations, and deaths, by vaccination status—13 US jurisdictions, April 4–July 17, 2021. Morbidity and Mortality Weekly Report. 2021 Sep 17;70(37):1284.

⁵⁸ Delahoy MJ, Ujamaa D, Whitaker M, O'Halloran A, Anglin O, Burns E, Cummings C, Holstein R, Kambhampati AK, Milucky J, Patel K. Hospitalizations associated with COVID-19 among children and adolescents—COVID-NET, 14 states, March 1, 2020–August 14, 2021. Morbidity and Mortality Weekly Report. 2021 Sep 10;70(36):1255.

⁵⁹ Siegel DA, Reses HE, Cool AJ et al. Trends in COVID-19 cases, emergency department visits, and hospital admissions among children and adolescents aged 0–17 years—United States, August 2020–August 2021. Morbidity and Mortality Weekly Report. 2021 Sep 10;70(36):1249.

To reduce introduction and spread of 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 curtail the introduction of other new variants into the United States.

This Amended Order is not a rule within the meaning of the 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, 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 Delta variant or other emerging variants through not fully vaccinated passengers who become infectious during the 3-day window currently allowed for predeparture testing.

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 virus 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. These actions are necessary to reduce the risk of transmission of new SARS-CoV-2 virus, including virus variants, and to protect the health of fellow travelers 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 for Fully Vaccinated*, a *Qualifying Test for Not Fully Vaccinated*, or *Documentation of Recovery*.
 - 1) Requirements for a *Qualifying Test for Fully Vaccinated* include:
 - a. Documentation of a negative SARS-CoV-2 viral test result from a specimen collected no more than **3 calendar days** preceding the passenger's flight to the United States. The negative SARS-CoV-2 viral test result should 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 **3 days** before the flight's departure (or first flight in a series of connections booked on the same itinerary);⁶⁰
 - iii. 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

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⁶⁰ Passengers traveling on a series of connections booked on the same itinerary also have the option of obtaining the required negative test result en route to the United States if testing within the required time frame is not available at their point of origin.

- "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
- information about the entity issuing the result (e.g., laboratory, healthcare entity, or telehealth service), such as the name and contact information; and
- b. Proof of Being Fully Vaccinated Against COVID-19 against COVID-19 as defined in this Amended Order, that includes personal identifiers (e.g., name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents.

2) Requirements for a *Qualifying Test for Not Fully Vaccinated* include:

- a. Documentation of a negative SARS-CoV-2 viral test result from a specimen collected no more than 1 day preceding the passenger's flight to the United States. The negative SARS-CoV-2 viral test result should include:
 - 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. specimen collection date indicating that the specimen was collected no more than 1 day before the flight's departure (or first flight in a series of connections booked on the same itinerary);⁶¹
 - iii. type of viral test indicating it is a NAAT or antigen test;
 - a test result that states "NEGATIVE," "SARS-CoV-2 RNA NOT iv. 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
 - information about the entity issuing the result (e.g., laboratory, healthcare entity, or telehealth service), such as the name and contact information.

3) Requirements for *Documentation of Recovery* include:

- Documentation of a positive SARS-CoV-2 viral test result from a specimen collected no more than three months (90 calendar days) preceding the passenger's flight to the United States, or at such other intervals as specified in CDC guidance. ⁶² The positive SARS-CoV-2 viral test result should 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;

⁶¹ Ibid.

⁶² Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19 https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html.

- 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-CoV-2 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.
- b. A signed letter from a licensed healthcare provider or a public health official stating that the passenger has been cleared for travel. 63,64 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 for Fully Vaccinated* plus being fully vaccinated, a negative result for a *Qualifying Test for Not Fully Vaccinated*, 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**.
- C. Not board any passenger without confirming the documentation as set forth in A and 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. However, CDC does not intend to rely on this enforcement mechanism for airlines or aircraft operators who accept paper or digital documentation of vaccination (i.e., paper or digital vaccination records, or verifiable vaccination credential) from a passenger in good faith and use best efforts to fulfill the requirements of this Amended Order.

2. Requirements for Aircraft Passengers

⁶³ Healthcare 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.

⁶⁴ 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.

Any aircraft passenger 65,66 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 for Fully Vaccinated that has a specimen collection date indicating that the specimen was collected no more than 3 calendar days before the flight's departure (or first flight in a series of connections booked on the same itinerary)⁶⁷ plus Proof of Being Fully Vaccinated Against COVID-19 against COVID-19:
 - 2) A negative *Qualifying Test for Not Fully Vaccinated* that has a specimen collection date indicating that the specimen was collected no more than **1 day** before the flight's departure (or first flight in a series of connections booked on the same itinerary); ⁶⁸ or
 - 3) *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. ^{69,70}
- B. Provide the attestation to the airline or other aircraft operator, of one of the following:
 - 1) having received a negative result for the *Qualifying Test for Vaccinated* and being fully vaccinated against COVID-19;

⁶⁵ 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).

⁶⁶ Children between the ages of 2 and 17 who are not fully vaccinated may board a flight to the United States with a negative pre-departure COVID-19 viral test conducted on a specimen collected no more than 3 calendar days before departure (i.e., Qualifying Test for Fully Vaccinated) if traveling accompanied by fully vaccinated parents or guardians. If traveling unaccompanied or if one or more of the parents or guardians accompanying the child is not fully vaccinated, the child must present a negative pre-departure COVID-19 viral test on a specimen collected no more than 1 day before departure (i.e., a Qualifying Test for Not Fully Vaccinated).

⁶⁷ Passengers traveling on a series of connections booked on the same itinerary also have the option of obtaining the required negative test result en route to the United States if testing within the required time frame is not available at their point of origin.

⁶⁸ Ibid.

⁶⁹ 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.

⁷⁰ Healthcare 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.

- 2) having received a negative result for the *Qualifying Test for Not Fully Vaccinated*; or
- 3) 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 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 in 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 additional variants of concern and/or the effectiveness of COVID-19 vaccines, CDC may exercise its enforcement discretion to broaden the scope of accepted vaccines or combinations of accepted vaccines 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 at 12:01am EST (5:01am GMT) on November 8, 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 October 25, 2021.

Hostalle f 12 september

Rochelle P. Walensky, MD, MPH Director, Centers for Disease Control and Prevention