

LUCAS WALL

3601 Cosmos Way
The Villages, FL 32163-2818
Phone: 202-351-1735
E-Mail: Lucas.Wall@yahoo.com

January 22, 2023

David Smith
Clerk of Court
U.S. Court of Appeals for the 11th Circuit
Filed Electronically

RE: *Wall v. Centers for Disease Control & Prevention*, No. 22-11532

Dear Mr. Smith:

I write to supplement the record with an important development that affects this appeal. As I noted in my reply brief filed Jan. 4, 2023, Appellee/Defendant Centers for Disease Control & Prevention (“CDC”) reinstituted the challenged International Traveler Testing Requirement (“ITTR” or “Testing Requirement”) effective Jan. 5. 88 Fed. Reg. 864. The government has not filed the latest version of the ITTR with the Court, so that is attached for the record on appeal.

I maintain standing to challenge the Testing Requirement because I travel frequently around the world including to China and Hong Kong. I have not yet been to Macau, but do intend to visit there sometime this year. This latest ITTR thus directly impacts my ability to travel abroad to the destinations I desire.

With this ITTR in effect, I will not travel to China, Hong Kong, or Macau due to concerns about getting stranded there should I be unable to find an acceptable test during the strict timeframe required, receive a false positive, or test positive for coronavirus. Being mandated to test for a virus in a foreign country as a condition of returning home to my country of citizenship is a major burden, both in time and money.

As I have argued, CDC lacks statutory authority from Congress to quarantine American citizens in a foreign country. Nor does the Constitution allow an administrative agency to interfere with the constitutional right to travel. Furthermore, CDC issued this latest ITTR without notice and comment as required by the Administrative Procedure Act, and the Court should also

strike it down for being arbitrary and capricious – there is no reason to single out these three foreign territories when COVID-19 has been circulating around the globe for three years.

Yours truly,

Lucas Wall

Appellant/Plaintiff

questions for the Committee or whether they wish to present during the meeting.

Additionally, using the registration page, registrants will be able to submit questions for the Committee or whether they wish to present during the meeting.

Special Accommodations

For information on services for individuals with disabilities, or to request accommodation of a disability, please contact Shenaye Holmes at shenaye.holmes@gsa.gov at least 10 business days prior to the meeting to give GSA as much time as possible to process the request. Closed captioning and live ASL interpreter services will be available.

Shenaye Holmes,

Senior Advisor, Office of Shared Solutions and Performance Improvement, General Services Administration.

[FR Doc. 2022-28596 Filed 1-4-23; 8:45 am]

BILLING CODE 6820-14-P

GENERAL SERVICES ADMINISTRATION

[Notice-MA-2022-11; Docket No. 2021-0002, Sequence No. 31]

Calendar Year (CY) 2023 Privately Owned Vehicle (POV) Mileage Reimbursement Rates; CY 2023 Standard Mileage Rate for Moving Purposes

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice.

SUMMARY: GSA is updating the mileage reimbursement rate for privately owned automobiles (POA), airplanes, and motorcycles as required by statute. This information will be available in FTR Bulletin 23-05, which can be found on GSA's website at <https://gsa.gov/ftrbulletins>.

DATES: *Applicability date:* This notice applies to travel and relocation performed on or after January 1, 2023 through December 31, 2023.

FOR FURTHER INFORMATION CONTACT: For clarification of content, please contact Ms. Cheryl D. McClain-Barnes, Policy Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202-208-4334, or by email at travelpolicy@gsa.gov. Please cite Notice of FTR Bulletin 23-05.

SUPPLEMENTARY INFORMATION: GSA is required by statute to set the mileage reimbursement rate for privately owned automobiles (POA) as the single standard mileage rate established by the

Internal Revenue Service (IRS). The IRS mileage rate for medical or moving purposes is used to determine the POA rate when a Government-furnished automobile is authorized and also represents the privately owned vehicle (POV) standard mileage reimbursement rate for official relocation. Finally, GSA conducts independent reviews of the cost of travel and the operation of privately owned airplanes and motorcycles on an annual basis to determine their corresponding mileage reimbursement rates. These reviews evaluate various factors, such as the cost of fuel, depreciation of the original vehicle cost, maintenance and insurance, state and Federal taxes, and consumer price index data. FTR Bulletin 23-05 establishes and announces the new CY 2023 POV mileage reimbursement rates for official temporary duty and relocation travel. This notice is the only notification to agencies of revisions to the POV mileage rates for official travel and relocation, in addition to the changes posted on GSA's website at <https://gsa.gov/mileage>.

Saul Japson,

Acting Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2022-28592 Filed 1-4-23; 8:45 am]

BILLING CODE 6820-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Requirements for Negative Pre-Departure COVID-19 Test Results or Documentation of Recovery From COVID-19 for Aircraft Passengers Traveling to the United States From the People's Republic of China

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: General notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), announces an Order requiring negative pre-departure COVID-19 test results or documentation of recovery from COVID-19 for aircraft passengers traveling to the United States from the People's Republic of China or departing from a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to their departure for the United States.

DATES: This Order will enter into effect for flights departing at or after 12:01 a.m. EST on January 5, 2023.

FOR FURTHER INFORMATION CONTACT: Candice Swartwood, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329. Telephone: 404-639-8897; Email: dgmqpolicyoffice@cdc.gov.

SUPPLEMENTARY INFORMATION: This Order requires negative pre-departure COVID-19 test results or documentation of recovery from COVID-19 for aircraft passengers traveling to the United States from the People's Republic of China.

Pursuant to 42 CFR 71.20 and 71.31(b), the Order prohibits the boarding of passengers 2 years of age or older on an itinerary that includes the United States^{1 2} on:

- any aircraft departing from the People's Republic of China, or
- any aircraft departing from a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to their departure for the United States, unless the passenger presents paper or digital documentation of one of the following requirements:

(a) A negative viral test result for SARS-CoV-2³ conducted on a specimen collected no more than 2 calendar days before the flight's departure from the People's Republic of China or 2 calendar days before the flight's departure from a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to their departure for the United States (*Qualifying Test*)

OR

(b) Documentation of having recovered from COVID-19 in the past 90 days in the form of one of the following (*i.e., Documentation of Recovery*):

- i. A positive viral test result for SARS-CoV-2 conducted on a specimen collected more than 10 calendar days but fewer than 91 calendar days before the flight's departure; OR
- ii. A positive viral test result for SARS-CoV-2 conducted on a specimen collected 10 or fewer calendar days before the flight's departure AND a

¹ This also includes any flight regardless of whether the United States is the final destination or an intermediate stop.

² 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 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).

³ SARS-CoV-2 is the virus that causes COVID-19.

signed letter from a licensed healthcare provider or public health official stating that the passenger's COVID-19 symptoms began more than 10 calendar days before the flight's departure.

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

(a) A negative result for the *Qualifying Test*; or

(b) *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.

This Order constitutes a controlled free pratique to any airline or other aircraft operator with an aircraft boarding passengers subject to the requirements of this Order at an airport in the People's Republic of China or a *Designated Airport*. Pursuant to this controlled free pratique, the airline or other aircraft operator must comply with the conditions outlined in the Order.

A copy of the Order is provided below. A copy of the signed Order and Passenger Attestation can be found at <https://www.cdc.gov/quarantine/china-proof-negative-test.html>.

Centers for Disease Control and Prevention (CDC)

Department of Health and Human Services (HHS)

Notice and 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 Aircraft Passengers Traveling to the United States From the People's Republic of China

Summary

Pursuant to 42 CFR 71.20 and 71.31(b) and as set forth in greater detail below, this Notice and Order prohibits the boarding of passengers 2 years of age or older on an itinerary that includes the United States^{4,5} on:

- any aircraft departing from the People's Republic of China, or
- any aircraft departing from a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to their departure for the United States, unless the passenger presents paper or digital documentation of one of the following requirements:

(c) A negative viral test result for SARS-CoV-2⁶ conducted on a specimen collected no more than 2 calendar days before the flight's departure from the People's Republic of China or 2 calendar days before the flight's departure from a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to their departure for the United States (*Qualifying Test*)

OR

(d) Documentation of having recovered from COVID-19 in the past 90 days in the form of one of the following (i.e., *Documentation of Recovery*):

iii. A positive viral test result for SARS-CoV-2 conducted on a specimen collected more than 10 calendar days but fewer than 91 calendar days before the flight's departure; OR

iv. A positive viral test result for SARS-CoV-2 conducted on a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or public health official stating that the passenger's COVID-19 symptoms began more than 10 calendar days before the flight's departure.

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

(c) A negative result for the *Qualifying Test*; or

(d) *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.

This Order applies regardless of citizenship or vaccination status. This Order excludes passengers transiting the People's Republic of China (for a period of 24 hours or less) en route to the United States. This Order also excludes passengers who have been in the People's Republic of China for less than 24 hours.

Pursuant to 42 CFR 71.31(b), and as set forth in greater detail below, this

Notice and Order constitutes a controlled free pratique to any airline or other aircraft operator with an aircraft boarding passengers subject to the requirements of this Order at an airport in the People's Republic of China or a *Designated Airport*. 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:⁷

- Airline or other aircraft operator must confirm that every passenger subject to the requirements of this Order 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 subject to the requirements of this Order onboard the aircraft has attested to one of the following:

- Having received a negative result for the *Qualifying Test*, or

- Having met the criteria for *Documentation of Recovery* by:

- testing positive for SARS-CoV-2 on a specimen collected more than 10 calendar days but fewer than 91 calendar days before the flight's departure, or

- developing COVID-19 symptoms more than 10 full calendar days before the flight's departure if their positive test is dated 10 or fewer calendar days before the flight.

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

- Amended Order Implementing Presidential Proclamation on Advancing the Safe Resumption of Global Travel During the COVID-19 Pandemic (published at 86 FR 61224, April 4, 2022); 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 Order shall enter into effect for flights departing at or after 12:01 a.m. EST (5:01 a.m. GMT) on January 5, 2023.

⁴ This also includes any flight regardless of whether the United States is the final destination or an intermediate stop.

⁵ 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 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).

⁶ SARS-CoV-2 is the virus that causes COVID-19.

⁷ Under 42 CFR 71.31(b), CDC may condition a carrier's arrival into the United States by issuing a controlled free pratique without requiring the detention of an arriving carrier. This controlled free pratique applies to any airlines and aircraft operators operating aircraft boarding passengers subject to the requirements of this Order. This controlled free pratique operates in aid of CDC's authority under 42 CFR 71.20 to conduct public health prevention measures to detect the potential presence of communicable disease.

Statement of Intent

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

- Preservation of human life;
- Preventing or delaying the introduction, transmission, and spread of any new variants of the virus that causes COVID-19 that may be circulating or emerge in the People's Republic of China;
- Preserving the health and safety of crew members, passengers, airport personnel, and communities; and
- Preserving hospital, healthcare, and emergency response resources and capacity 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.

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. 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. 1001.⁸

Designated Airports mean those airports outside of the People's Republic of China where the requirements of this Order apply. *Designated Airports* include Incheon International Airport (ICN) in Seoul, Republic of Korea; Toronto Pearson International Airport (YYZ) in Canada; Vancouver International Airport (YVR) in Canada; and other airports that CDC may list in guidance associated with this Order.⁹

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. The viral test must have been conducted on a specimen collected

more than 10 calendar days but fewer than 91 calendar days before the departure of the flight, or at such other intervals as specified in CDC guidance. Alternatively, *Documentation of Recovery* may consist of a positive SARS-CoV-2 viral test result from a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or public health official stating that the passenger's symptoms began more than 10 full calendar days before the flight's departure.

People's Republic of China for the purpose of this Notice and Order means the People's Republic of China, including the Special Administrative Regions of Hong Kong and Macau.

Qualifying Test means a SARS-CoV-2 viral test that was conducted on a specimen collected no more than two (2) calendar days before the passenger's departure from the People's Republic of China, or a *Designated Airport* if the passenger has been in the People's Republic of China within the ten (10) days prior to departure for 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 with SARS-CoV-2, i.e., a nucleic acid amplification test (NAAT) or a viral antigen test. The test must be cleared, approved, or issued an emergency use authorization by the U.S. Food and Drug Administration, or granted marketing authorization by the relevant national authority, for the detection of SARS-CoV-2.

Exceptions

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

- Crew members of airlines or other aircraft operators if they are on official duty assigned by the airline or aircraft operator that involves operation of the aircraft or positioning of crew not operating the aircraft, provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID-19 consistent with relevant CDC guidance.

- Airlines or other aircraft operators transporting passengers with COVID-19

on flights other than scheduled passenger airline flights pursuant to CDC authorization¹⁰ and with infection control measures in place to prevent onboard transmission consistent with relevant CDC guidance.

- 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) or non-U.S. military flights, if such individuals are under competent military or U.S. Government travel orders and observing applicable U.S. Department of Defense force health protection guidance to prevent the transmission of COVID-19.

- Individuals for whom the issuance of a humanitarian exception 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 pre-departure testing cannot be accessed or completed before travel because of exigent circumstances.

Background

A. COVID-19 in the People's Republic of China and Emergence of Virus Variants of Concern

COVID-19 is surging in the People's Republic of China.¹¹ Mitigation

¹⁰ Federal regulations at 42 CFR 71.21(b) requires the commander of an aircraft destined for a U.S. airport to report immediately to the quarantine station at or nearest the airport at which the aircraft will arrive, the occurrence, on board, of any death or ill person among passengers or crew.

¹¹ On June 10, 2022, CDC rescinded the Order titled “Requirement for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery from COVID-19 for All Airline or Other Aircraft Passengers Arriving in the United States from any Foreign Country.” As part of its rescission, CDC stated that it would periodically reassess the need for a testing requirement based on the latest science, virus variants, and evolving state of the pandemic, and could reinstitute testing if necessary to protect the public's health. The current Order is a more targeted application of the testing requirement to address specifically the lack of available information in global databases about virus variants potentially circulating in the People's Republic of China. Although many of the factors cited in the June 10 rescission that strengthen community and individual protection against serious illness from COVID-19, including efficacious and accessible treatments continue to

⁸ 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.

⁹ In adding new airports, CDC will consider data regarding travel patterns of passengers departing the People's Republic of China on itineraries to the United States, as well as additional information concerning the emergence of virus variants.

measures are largely not in use, and there are significant gaps in data and information on cases, hospitalizations, deaths, and genomic sequences. The population in the People's Republic of China lacks extensive exposure to the virus that causes COVID-19 and therefore lacks substantial immune protection through prior infection. The recent surge in COVID-19 transmission, particularly in a large population such as the People's Republic of China, increases the potential for new SARS-CoV-2 variants to emerge that could be introduced to the United States.

Although virus variants continue to emerge in countries around the world, the lack of viral genomic sequence data from the People's Republic of China in global databases could delay the identification of new virus variants of concern if they arise. These data are critical to monitor the surge effectively and to allow U.S. public health officials to identify any potential virus variants of concern.

New virus variants have the potential to evade the immune protection acquired in the U.S. population through vaccination and prior illness. The emergence of virus variants that substantially decrease the effectiveness of available vaccines against severe or deadly COVID-19, and decrease the effectiveness of therapeutics and diagnostics, is a primary public health concern for the United States. Additionally, new virus variants could be associated with increases in transmissibility (higher infection rates) or severity (higher rates of hospitalization or death) that have the potential to overwhelm U.S. healthcare systems, especially at a time when influenza and other respiratory viruses are circulating.¹²

Considering the danger to public health posed by potential emerging new virus variants in the People's Republic of China, CDC has determined that additional proactive, preventative measures must be implemented now to protect the U.S. population from potential importation, transmission and spread of new virus variants into the United States. Pre-departure testing and the requirement to show a negative test result decrease the number of infected passengers boarding airplanes and constitute a proactive, risk-based approach. This will help to slow the spread of COVID-19 as we work to identify and understand any potential

new virus variants that may emerge. This risk-based testing approach has been addressed in CDC guidance.¹³

CDC acknowledges that pre-departure testing does not eliminate all risk and some positive COVID-19 cases may evade this detection measure. Some tests, including antigen tests, may have lower sensitivity for the virus that causes COVID-19. Some people who test negative within 2 days before their flight may also be exposed to or develop COVID-19 after being tested. Therefore, CDC will implement this testing requirement simultaneously with other mitigation measures, including enhanced education and surveillance strategies.

CDC is expanding the Traveler-based Genomic Surveillance program (TGS), a voluntary program that collects anonymous nasal swabs from arriving international travelers at major U.S. international airports as an early warning system to detect and characterize new and rare variants of the virus that causes COVID-19. The program tests for presence of the virus, and if it is detected, the program sequences the virus's genome to identify any new variants. The program is expanding in order to support increased information about potential virus variants imported from the People's Republic of China.

As part of the Traveler-based Genomic Surveillance program, arriving international travelers on selected flights can volunteer to provide anonymous nasal swabs for testing. The nasal swabs get batched into pools and all positive batches undergo genomic sequencing for the virus, allowing for the quick detection of virus variants from international travelers. This program has proven to overcome gaps in global SARS-CoV-2 variant surveillance that occur as many countries decrease or discontinue testing and sequencing. During the initial weeks of the Omicron surge, TGS detected two Omicron subvariants, BA.2 and BA.3, and reported them to the global database weeks before they were reported elsewhere, demonstrating that the program is able to detect new virus variants early.

Pre-departure testing and the requirement to show a negative test reduces the introduction, transmission, and spread into the United States of virus variants. These measures provide a safer environment for travelers and protect the health of people in the United States, particularly when layered

with existing CDC recommendations such as masking during travel, self-monitoring for symptoms, and testing three to five days after arrival from international travel.

B. Statement of Good Cause Under the Administrative Procedure Act ("APA")

The recent surge in COVID-19 cases in the People's Republic of China may result in the emergence of new virus variants that can increase transmissibility or severity or compromise the effectiveness of current medical countermeasures. Because of policies of the People's Republic of China relating to COVID-19, the population has not developed immune protection and is more susceptible to infection when compared with other countries. Travelers are an important population to consider when tracking new and emerging infectious diseases because they move from place to place quickly and can contract and spread infectious diseases. Pre-departure testing and the requirement to show a negative test helps prevent infected travelers from boarding flights to the United States and slows the introduction, transmission, and spread of virus variants into the United States. The introduction of infected travelers and potential emergence of virus variants of concern are of particular concern at this time, when the United States' healthcare system is already facing surges in other respiratory viruses.

Based on the lack of viral genomic sequence data from the People's Republic of China, this action is necessary imminently to allow U.S. public health officials the critical time needed to monitor the unprecedented surge of COVID-19 in the People's Republic of China effectively and to identify any potential variants of concern. CDC will continue to monitor the situation and be prepared to quickly adjust its approach as necessary to protect the public's health.

Due to the current volume of passengers from the People's Republic of China transiting through Incheon International Airport, Toronto Pearson International Airport, and Vancouver International Airport on their way to the United States, I have determined that prompt action is needed with respect to travelers departing from these airports if they have been in the People's Republic of China in the last 10 days. CDC, in coordination with other Federal agencies, will continue to monitor travel patterns between the People's Republic of China and the United States and adjust its approach as needed.

exist, CDC has concluded that the current Order is needed to protect the public's health.

¹² Influenza Hospitalization Surveillance Network (FluSurv-NET): <https://www.cdc.gov/flu/weekly/influenza-hospitalization-surveillance.htm>.

¹³ COVID-19 Testing: What You Need to Know <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html#when-to-get-tested>.

This 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 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 surge in cases in the People’s Republic of China, 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 Order. Further delay could increase risk of transmission and importation of undetected emerging virus variants through passengers. New virus variants could be associated with increases in transmissibility (higher case rates), severity (higher rates of hospitalization or death), and have the potential to overwhelm U.S. healthcare systems, especially at a time when influenza and other respiratory viruses are circulating.

Similarly, the Office of Information and Regulatory Affairs has determined that if this 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 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.

Pursuant to 5 U.S.C. 553(b)(B), and for the reasons stated above, I hereby conclude that good cause exists to dispense with notice-and-comment rulemaking because engaging in such rulemaking is impractical, would endanger the public health, and thus, be 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 Order effective for flights departing at or after 12:01 a.m. EST (5:01 a.m. GMT) on January 5, 2023.

C. Severability

If any provision of this Order, or the application of any provision to any carriers, persons, or circumstances, shall be held invalid, I intend that 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. Although the application of all of this Order’s provisions uniformly across all carriers, persons, and circumstances will maximize the Order’s protection of health and safety, the various provisions and applications of this Order operate independently and independently further the purposes of this Order. Thus, in the event of a stay or invalidation of any provision of the Order, or of the Order as it applies to any carrier, person, or circumstances, my intent is that the remainder of the Order remain in effect.

Action

For the reasons outlined above, I hereby determine that passengers subject to the requirements of this Order are at risk of transmitting new SARS-CoV-2 variants that may be circulating or emerge in the People’s Republic of China. Accordingly, requiring these passengers to present either a negative COVID-19 test result or recovery from COVID-19 in the past 90 days is necessary to reduce the risk of introduction, transmission and spread of new SARS-CoV-2 variants, and to protect the health of fellow passengers, aircraft crew, and U.S. communities. This Order shall remain effective until I determine that based on specific public health or other considerations that continuation of this Order is no longer necessary to prevent the introduction, transmission, and spread of new SARS-CoV-2 variants into the United States. Upon determining that continuation of this Order is no longer necessary to prevent the introduction, transmission, and spread of new SARS-CoV-2 variants 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 boarding passengers subject to the requirements of this Order shall:

A. Identify which passengers are subject to the requirements of this Order and confirm that each such passenger, prior to boarding the aircraft, has

presented paper or digital documentation reflecting a *Qualifying Test* or *Documentation of Recovery* or meets one of the specified exceptions.

(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 2 calendar days before the flight’s departure. 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 2 calendar days before the flight’s departure;

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 one of the following:

a. Documentation of a positive SARS-CoV-2 viral test result from a specimen collected more than 10 calendar days but fewer than 91 calendar days preceding the flight’s departure.¹⁴ 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 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 more than 10 calendar days but fewer than 91 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

¹⁴ Interim Guidance on Ending Isolation and Precautions for Adults with COVID-19 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html>.

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. Documentation of a positive SARS-CoV-2 viral test result from a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or a public health official stating that the passenger's COVID-19 symptoms began more than 10 calendar days before the flight's departure. The letter must list the date the person's symptoms started; have personal identifiers (e.g., name and date of birth) that match the personal identifiers on the passenger's passport or other travel documents; and 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. 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 that match the personal identifiers on the passenger's passport or other travel documents;

ii. information that the test performed was a viral test indicating it is a NAAT or antigen test;

iii. 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

iv. information about the entity issuing the result (e.g., laboratory, healthcare entity, or telehealth service), such as the name and contact information.

B. Confirm that each passenger has attested to having received a negative result for a *Qualifying Test* or having met the requirements for *Documentation of Recovery*. 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 this Order.

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 subject to the requirements of this Order 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 2 calendar days before the flight's departure; or

(2) *Documentation of Recovery* from COVID-19 that includes:

a. a positive SARS-CoV-2 viral test result conducted on a specimen collected more than 10 calendar days but fewer than 91 calendar days preceding the passenger's scheduled flight to the United States; OR

b. documentation of a positive SARS-CoV-2 viral test result from a specimen collected 10 or fewer calendar days before the flight's departure AND a signed letter from a licensed healthcare provider or a public health official stating that the passenger's COVID-19 symptoms began more than 10 days before the flight's departure.

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 met the requirements for *Documentation of Recovery*.

The attestation is attached to this order as Attachment A. 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 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 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 COVID-19 pandemic continues to rapidly evolve and more scientific data becomes available regarding potential emerging

virus variants in the People's Republic of China, 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 Order or to align with current CDC guidance. Such exercises of enforcement discretion will be announced on CDC's website and the Order will be amended as soon as practicable through an updated publication in the **Federal Register**.

Effective Date

This Order shall enter into effect for flights departing at or after 12:01 a.m. EST (5:01 a.m. GMT) on January 5, 2023, and will remain in effect unless modified or rescinded based on specific public health or other considerations.

Authority

The authority for this Order is Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 71.20 & 71.31(b).

Dated: January 3, 2023.

Sherri Berger,

Chief of Staff, Centers for Disease Control and Prevention.

Attachment A

Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers From the People's Republic of China

Notice to Airlines and Aircraft Operators

This passenger disclosure and attestation fulfills the requirements of U.S. Centers for Disease Control and Prevention (CDC) Order: *Requirements for Negative Pre-Departure COVID-19 Test Result or Documentation of Recovery from Covid-19 for All Airline or Other Aircraft Passengers Traveling to the United States from the People's Republic of China*.^{15 16}

Airline and Aircraft Operator Disclosure Requirements

As required by United States Federal law, all airlines or other aircraft

¹⁵ This requirement (*i.e.*, proof of negative COVID-19 test or recovery) does not apply to crewmembers of airlines or other aircraft operators on official duty assigned by the airline or aircraft operator that involves operation of the aircraft or repositioning of crew (*i.e.*, on "deadhead" status), provided their assignment is under an air carrier's or operator's occupational health and safety program that follows applicable industry standard protocols for the prevention of COVID-19 consistent with relevant CDC guidance. See the Order and CDC's website for more information about applicability and exceptions.

¹⁶ People's Republic of China includes the Special Administrative Regions of Hong Kong and Macau.

operators must collect the passenger attestation on behalf of the U.S. Government.¹⁷

As required by the Order, all airlines and other aircraft operators must provide this disclosure to all air passengers who are ages 2 years and older¹⁸ who have an itinerary that includes the United States and are boarding:

(1) an aircraft in the People's Republic of China, or

(2) an aircraft at a *Designated Airport* if the passenger has been in the People's Republic of China in the past 10 calendar days. *Designated Airports* include Incheon International Airport (ICN) in Seoul, Republic of Korea; Toronto Pearson International Airport (YYZ) in Canada; and Vancouver International Airport (YVR) in Canada.

This requirement does not apply to passengers transiting through an airport in the People's Republic of China en route from another country to the United States. It also does not apply to passengers who have been in the People's Republic of China for less than 24 hours.

The airline must identify which passengers are subject to the requirements of this Order and confirm that each such passenger, prior to boarding the aircraft, has presented paper or digital documentation reflecting:

A. A negative result for a COVID-19 viral test taken no more than 2 days before the departure of the flight from an airport in the People's Republic of China or a *Designated Airport*; or

B. *Documentation of Recovery* from COVID-19 in the form of:

■ A positive viral test result for COVID-19 conducted on a sample collected more than 10 calendar days but fewer than 91 calendar days before the departure of the flight from an airport in the People's Republic of China or a *Designated Airport*; or

■ A positive viral test result for COVID-19 conducted on a sample taken 10 or fewer calendar days before the flight AND a signed letter from a licensed healthcare provider or public health official stating that the passenger's symptoms began more than 10 calendar days before the departure of the flight from an airport in the People's Republic of China or a *Designated Airport*; or

¹⁷ This attestation does not need to be completed by or on behalf of children under 2 years of age. The airline or other aircraft operator may permit them to board an aircraft without an attestation.

¹⁸ This Order applies to any passenger 2 years of age or older, regardless of citizenship or vaccination status.

C. A *Humanitarian Exception* in the form of a letter from the U.S. Government

OMB Control No.: 0920-XXXX

Proof of Negative Covid-19 Test Result or Documentation of Recovery for Air Passengers From the People's Republic of China¹⁹

Passenger Disclosure and Attestation

The information provided below must be accurate and complete to the best of the person's knowledge. Under United States Federal law, the attestation must be completed for each air passenger 2 years of age or older who has an itinerary that includes the United States and is boarding an aircraft in the People's Republic of China; or is boarding an aircraft at a *Designated Airport* and has been in the People's Republic of China in the last 10 calendar days. Failure to complete and present the applicable portion of the attestation, or submitting false or misleading information, could result in delay of travel, denial of boarding, or denial of boarding on future travel, or put the passenger or other people at risk of harm, including serious bodily injury or death. Any passenger who fails to comply with these requirements may be subject to criminal penalties. Willfully providing false or misleading information may lead to criminal fines and imprisonment under, among other provisions, 18 U.S.C. 1001. Providing this information can help protect you, your friends and family, your communities, and the United States. The U.S. Centers for Disease Control and Prevention (CDC) appreciates your cooperation.

One attestation form must be filled out for each air passenger 2 years of age or older with an itinerary that includes the United States prior to boarding

(1) an aircraft in the People's Republic of China; or

(2) an aircraft at a *Designated Airport* if the passenger has been in the People's Republic of China in the last 10 days. *Designated Airports* include Incheon International Airport (ICN) in Seoul, the Republic of Korea; Toronto Pearson International Airport (YYZ) in Canada; and Vancouver International Airport (YVR) in Canada.²⁰

¹⁹ People's Republic of China includes the Special Administrative Regions of Hong Kong and Macau.

²⁰ This requirement excludes persons transiting through an airport in the People's Republic of China en route to the United States from another country. This Order also excludes persons who have been in the People's Republic of China for less than 24 hours.

Public reporting burden of this collection of information is estimated to average 2 hours per response, including the time for reviewing

The air passenger or the person acting on behalf of the air passenger as a legal representative, such as a parent or guardian, must check A, B, or C and sign the attestation.

I, _____ am attesting on

(Select one):

PRINT FIRST AND LAST NAME

☐ My own behalf

☐ Behalf of:

PRINT FIRST AND LAST NAME

A. Negative Pre-Departure Test Result

☐ I attest that I have (or the person I am attesting on behalf of has) received a negative test result for COVID-19. The test was a viral test that was done on a sample taken from me (or the person) no more than 2 calendar days before my (or the person's) flight's departure.

B. Documentation of Recovery From COVID-19

☐ I attest that I have (or the person I am attesting on behalf of has) met the criteria for documentation of recovery by:

- testing positive for COVID-19 that was done on a sample taken from me (or the person) more than 10 calendar days but fewer than 91 calendar days before my (or the person's) flight's departure;

or

- developing COVID-19 symptoms more than 10 full calendar days before my (or the person's) flight's departure if my (or the person's) positive viral test was done on a sample taken from me (or the person) 10 or fewer calendar days before my (or the person's) flight.

C. Humanitarian Exception

☐ I attest that I have (or the person I am attesting on behalf of has) received a humanitarian exception to the requirement to show a negative COVID-19 test result or documentation of recovery, documented by a letter provided by the U.S. Government.

Print Name

instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. Comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, may be submitted to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA 0920-XXXX.

Signature

Dated

Privacy Act Statement for Air Passengers From People's Republic of China Relating to the Requirement To Provide Proof of a Negative COVID-19 Test Result or Documentation of Recovery

The U.S. Centers for Disease Control and Prevention (CDC) requires airlines and other aircraft operators to collect this information pursuant to 42 CFR 71.20 and 71.31(b), as authorized by 42 U.S.C. 264. Providing this information is mandatory for all passengers 2 years and older boarding an aircraft into the United States from the People's Republic of China, or from *Designated Airports* if they have been in the People's Republic of China in the last 10 days.

Failure to provide this information may prevent you from boarding the plane. Additionally, passengers will be required to attest to providing complete and accurate information, and failure to do so may lead to other consequences, including criminal penalties. CDC will use this information to help prevent the introduction, transmission, and spread of communicable diseases.

The Privacy Act of 1974, 5 U.S.C. 552a, governs the collection and use of this information about citizens of the United States and aliens lawfully admitted for permanent residence. The information maintained by CDC will be covered by CDC's System of Records No. 09-20-0171, Quarantine- and Traveler-Related Activities, Including Records for Contact Tracing Investigation and Notification under 42 CFR parts 70 and 71. See 72 FR 70867 (Dec. 13, 2007), as amended by 76 FR 4485 (Jan. 25, 2011) and 83 FR 6591 (Feb. 14, 2018). CDC will only disclose information from the system outside the CDC and the U.S. Department of Health and Human Services as the Privacy Act permits, including in accordance with the routine uses published for this system in the **Federal Register**, and as authorized by law. Such lawful purposes may include, but are not limited to, sharing identifiable information with state and local public health departments, and other cooperating authorities. CDC and cooperating authorities will retain, use, delete, or otherwise destroy the designated information in accordance with Federal law and the System of Records Notice (SORN) set forth above. You may contact the system manager at dgmqpolicyoffice@cdc.gov or by mailing Policy Office, Division of Global

Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16-4, Atlanta, GA 30329, if you have questions about CDC's use of your data.

[FR Doc. 2023-00080 Filed 1-3-23; 4:15 pm]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0461]

Format and Content of a Risk Evaluation and Mitigation Strategy Document; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Format and Content of a REMS Document." This final guidance describes the format for a proposed risk evaluation and mitigation strategy (REMS) document. This format was created based on extensive stakeholder feedback. This guidance finalizes the revised draft guidance of the same title issued on October 12, 2017, and announces the availability of the technical specifications document entitled "REMS Document Technical Conformance Guide."

DATES: The announcement of the guidance is published in the **Federal Register** on January 5, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact

information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2009-D-0461 for "Format and Content of a REMS Document." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting