

## PICOTS (POPULATION, INTERVENTION, COMPARATOR, OUTCOME, TIMING, SETTING)—Continued

PICOTS	KQ1: pre-treatment nutritional interventions (PNIs)	KQ2: nutritional interventions during treatment (NIDTs)	KQ3: pre- or during treatment nutritional interventions (NIs) and patient-centered outcomes	KQ4: weight loss in overweight/obese adults with cancer
Timing .....	Nutritional interventions delivered pre- cancer treatment (KQ1, KQ3, KQ4) and during cancer treatment (KQ2, KQ3, KQ4).			
Setting .....	Outpatient Oncology Care, Ambulatory Care, Cancer Treatment Centers, inpatient, home-based, hospice, telemedicine.			

Abbreviations: KQ = key question; BMI = body mass index; ER = emergency room; PICOTS = population, intervention, comparator, outcomes, timing, setting; RCT = randomized controlled trial; NRCT = non-randomized controlled trial.

Dated: October 22, 2021.

**Marquita Cullom,**

*Associate Director.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) for Cruise Ships Operating or Intending To Operate in U.S. Waters

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

**ACTION:** Notice.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces a temporary extension and modification of the Framework for Conditional Sailing Order (CSO).

**DATES:** This action is effective November 1, 2021, at 12:01 a.m. EDT upon the expiration of the current Order.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Buigut, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329. Phone: 404–498–1600. Email: [dgmqpolicyoffice@cdc.gov](mailto:dgmqpolicyoffice@cdc.gov).

**SUPPLEMENTARY INFORMATION:** This Order temporarily extends and modifies the Framework for Conditional Sailing Order (CSO). This Order only applies to cruise ship operators in U.S. jurisdictions where foreign-flagged ships port or travel on international itineraries and state and local health departments do not routinely exercise public health jurisdiction nor maintain maritime public health programs that conduct surveillance, inspections, investigations, and management of communicable diseases with potential for significant morbidity and mortality onboard foreign-flagged ships. These

specific jurisdictions are listed below in the Order.

This Order additionally applies to foreign-flagged cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States during the period that this Order is in effect.

As per the Preliminary Injunction Order, entered by the U.S. District Court for the Middle District of Florida on June 18, 2021, as of July 23, 2021, the CSO and accompanying measures, such as technical instructions, are nonbinding recommendations for cruise ships arriving in, located within, or departing from a port in Florida. Accordingly, this Order shall not apply to this subset of ships while this Preliminary Injunction Order remains in effect (or in the event the Preliminary Injunction becomes permanent). However, CDC will continue to operate the CSO as a voluntary program for such ships should they choose to follow the CSO measures on a voluntary basis.

A copy of the Order is provided below and a copy of the signed order can be found at <https://www.cdc.gov/quarantine/cruise/index.html>.

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

#### Order Under Sections 361 & 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 Code of Federal Regulations Part 70 (Interstate) and Part 71 (Foreign)

#### Temporary Extension & Modification of Framework for Conditional Sailing Order (CSO)

##### Executive Summary

The Centers for Disease Control and Prevention is temporarily extending the Framework for Conditional Sailing Order (CSO) issued on October 30, 2020. Since the issuance of the CSO, cruise lines, with CDC assistance, have resumed passenger operations and successfully developed and implemented health and safety protocols to manage COVID–19 that

have averted overwhelming onboard medical facilities and burdening shoreside hospital resources. However, considering the continued spread of the Delta variant, emergence of other COVID–19 variants of concern, breakthrough cases among the fully vaccinated, and possible additional surges of cases and deaths, CDC has determined a temporary extension of the CSO is necessary for foreign-flagged cruise ships operating on international itineraries. After the expiration of this temporary extension, CDC intends to transition to a voluntary program, in coordination with interested cruise ship operators and other stakeholders, to assist the cruise ship industry to detect, mitigate, and control the spread of COVID–19 onboard cruise ships.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID–19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the Order based on specific public health or other considerations; or (3) January 15, 2022 at 12:01 a.m. (EST).

#### Previous Orders and Incorporation by Reference

The findings and other evidence relied upon in issuing the CSO are incorporated herein by reference. Any ambiguity between the October 30, 2020 Order, as further modified and extended by the current Order, shall be resolved in favor of the current Order.

#### Applicability

This temporary renewal and modification of the CSO shall apply only to the subset of carriers<sup>1</sup> described below and hereinafter referred to as “cruise ships”:

All commercial, non-cargo,<sup>2</sup> foreign-flagged,<sup>3</sup> passenger-carrying vessels operating

<sup>1</sup> Carrier is defined by 42 CFR 71.1 to mean, “a ship, aircraft, train, road vehicle, or other means of transport, including military.”

<sup>2</sup> Given the substantial risk of person-to-person transmission of COVID–19, as opposed to transmission via indirect contact, this Order is currently limited to passenger, non-cargo vessels.

<sup>3</sup> This Order modifies the CSO so that it is applicable only to foreign-flagged vessels that per 46 U.S.C. 55103 may not travel between U.S. ports

in U.S. waters with the capacity<sup>4</sup> to carry 250<sup>5</sup> or more individuals (passengers and crew), and with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.<sup>6</sup>

This Order shall additionally apply to foreign-flagged cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in international, interstate, or intrastate waterways, subject to the jurisdiction of the United States during the period that this Order is in effect.

As explained further in this Order, based on the CDC Director's determination of inadequate local control under 42 CFR 70.2,<sup>7</sup> this Order shall only apply to cruise ship operators in U.S. jurisdictions where foreign-flagged ships port or travel on international itineraries and state and local health departments do not routinely exercise public health jurisdiction nor maintain maritime public health programs that conduct surveillance, inspections, investigations, and management for communicable diseases with potential for significant

without including a stop at a foreign port in their itinerary. Because foreign-flagged vessels typically operate on international itineraries far from U.S. shores, outbreaks on such vessels are more likely to require emergency medical evacuations while at sea and thus burden U.S. Coast Guard and other emergency medical response resources. Furthermore, stopping in a foreign port increases the risk of introducing a COVID-19 variant of concern into the United States. [International Travel During COVID-19 | CDC].

<sup>4</sup> A ship's capacity shall be determined based on the number of persons listed in the U.S. Coast Guard Certificate of Compliance issued in accordance with 46 CFR 2.01-6 and that was in effect on October 30, 2020.

<sup>5</sup> CDC continues to define cruise ships as those with a capacity to carry 250 or more passengers and crew based on substantial epidemiologic evidence related to congregate settings and mass gatherings. While evidence shows that outbreaks can occur in small settings such as nursing homes, as the numbers of passengers and crew on board a ship increase, certain recommended mitigation efforts such as social distancing become more difficult to implement. Considering the demonstrated rapid spread of COVID-19, the application of this framework to cruise ships carrying 250 or more passengers and crew remains prudent and warranted.

<sup>6</sup> This Order shall not apply to vessels operated by a U.S. Federal or State government agency. Nor shall it apply to vessels being operated solely for purposes of the provision of essential services, such as the provision of medical care, emergency response, activities related to public health and welfare, or government services, such as food, water, and electricity.

<sup>7</sup> Because this Order applies only to foreign-flagged vessels that per 46 U.S.C. 55103 may not travel between U.S. ports without including a stop at a foreign port in their itinerary, 42 CFR 71.31(b), 71.32(b), constitute sufficient legal authority to support this Order. However, 42 CFR 70.2 provides additional legal authority and support to the extent that it is needed for the reasons explained in this Order.

morbidity and mortality<sup>8</sup> onboard foreign-flagged ships.<sup>9</sup>

As per the Preliminary Injunction Order, entered by the U.S. District Court for the Middle District of Florida on June 18, 2021, as of July 23, 2021, the CSO and accompanying measures, such as technical instructions, are nonbinding recommendations for cruise ships arriving in, located within, or departing from a port in Florida. Accordingly, this Order shall not apply to this subset of ships while this Preliminary Injunction Order remains in effect (or in the event the Preliminary Injunction becomes permanent). However, CDC will continue to operate the CSO as a voluntary program for such ships should they choose to follow the CSO measures on a voluntary basis.

#### Statement of Intent

This Order shall be interpreted and implemented in a manner as to achieve the following paramount objectives:

- Preserving human life;
- Preserving the health and safety of cruise ship crew members, port personnel, and communities;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of Federal, State, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

#### Summary of CSO Extension Compared to Previous CSO

This temporary extension of the CSO leaves major provisions of the previous CSO unchanged with only minor modifications to incorporate changes in technical instructions made based on

<sup>8</sup> In addition to quarantinable communicable diseases as defined under 42 CFR 70.1 and 71.1, communicable diseases with potential for significant morbidity and mortality include diseases that spread from person to person, such as respiratory diseases (e.g., varicella, mumps, pertussis, meningococcal disease) and norovirus, and those that arise from contaminated food, potable water, or recreational water (e.g., *Salmonella*, *Escherichia coli*, *Cryptosporidium*), or the environment, such as Legionnaires' disease.

<sup>9</sup> These jurisdictions include the following U.S. states: Alabama, Alaska, California, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, and Washington State. These jurisdictions also include the following U.S. territories: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. CDC is not currently aware of any states or U.S. territories operating a maritime public health program that would displace the CSO.

discussions and feedback from cruise ship operators and announced through "Dear Colleague" communications to industry partners. Accordingly, CDC does not view this temporary extension as imposing any new burdens or obligations on cruise ship operators when compared to the previous CSO. As further explained in this extension, the most significant change is to narrow the applicability of the CSO to "foreign-flagged" cruise ships operating in U.S. jurisdictions that do not routinely exercise public health jurisdiction nor maintain maritime public health programs that conduct surveillance, inspections, investigations, and management for communicable diseases with potential for significant morbidity and mortality onboard foreign-flagged ships.

Currently, there is only one cruise ship operator under the CSO that is not foreign-flagged and operates its ships exclusively in interstate waterways subject to the jurisdiction of the United States. Unlike ocean-going foreign-flagged vessels, in the event of an outbreak, interstate vessels typically operate in such a manner that, should an outbreak occur, passengers and crew can be quickly brought by ambulance to local hospitals without requiring airlifts or evacuations at sea that significantly burden U.S. Coast Guard or potentially overwhelm public health resources.<sup>10</sup> Interstate vessels also operate under the jurisdiction of the Food and Drug Administration's (FDA) Interstate Travel Program and are subject to additional federal oversight under the provisions of 21 CFR 1240, 1250. Accordingly, CDC believes that narrowing the application of the CSO in this manner does not jeopardize the public's health. Furthermore, should this cruise ship operator choose to do so, it may continue to follow the CSO on a voluntary basis.

CDC provides the following chart to further explain how key substantive

<sup>10</sup> Another cruise ship operator has one U.S.-flagged cruise ship that operates solely between Hawaiian Islands. Similar to interstate vessels, the ship can quickly make port and bring passengers and crew by ambulance to local hospitals without requiring airlifts or evacuations at sea that significantly burden U.S. Coast Guard or potentially overwhelm public health resources. While foreign-flagged cruise ships operating on the Great Lakes may, depending on their itineraries, be able to return to port more quickly than ocean-going vessels, based on their international itineraries they would not fall under FDA's Interstate Travel Program. Furthermore, as discussed elsewhere, state and local health departments are engaged in other COVID-19 response efforts. Accordingly, excluding foreign-flagged vessels operating international itineraries on the Great Lakes from the application of this Order would create a regulatory gap.

provisions of this temporary extension operate compared to the previous CSO:

CSO sections	Modifications
Acronyms, Initialisms, and Definitions .....	<ul style="list-style-type: none"> <li>• Definition of cruise ships narrowed by adding “foreign-flagged”.</li> </ul>
Purpose and Scope .....	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>
General Prohibition on a Cruise Ship Operator Commencing or Continuing Passenger Operations without a COVID–19 Conditional Sailing Certificate.	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>
Requirements for COVID–19 Response Plan for Cruise Ship Operators Operating or Intending to Operate Cruise Ships in U.S. Waters.	<ul style="list-style-type: none"> <li>• Previously referred to as “No Sail Order (NSO) Response Plans”.</li> </ul>
Requirements for COVID–19 Testing Capabilities and Reporting for Cruise Ship Operators Operating or Intending to Operate Cruise Ships in U.S. Waters.	<ul style="list-style-type: none"> <li>• No changes for operators with previously approved plans.</li> <li>• No new requirements: cruise ship operators completed requirements as part of previous CSO “Phase 1” crew testing.</li> </ul>
Agreement with Port and Local Health Authorities .....	<ul style="list-style-type: none"> <li>• Modified to incorporate current Technical Instructions for Crew.</li> <li>• Modified to incorporate current Port Agreement Technical Instructions.</li> </ul>
Minimum Standards for Simulated Voyages Prior to Issuance of COVID–19 Conditional Sailing Certificate.	<ul style="list-style-type: none"> <li>• Removed language referring to cruise ship operator protocols as “unproven and untested”.</li> <li>• Modified to incorporate current Technical Instructions for Simulated Voyages.</li> </ul>
Procedures in Lieu of Conducting a Simulated Voyage for Cruise Ship Operators Transitioning to Voyages with Less Than 95% of Passengers Fully Vaccinated.	<ul style="list-style-type: none"> <li>• New provision aimed at reducing potential industry burden for certain operators.</li> <li>• Based on “Dear Cruise Industry Colleagues” email sent on September 21, 2021. Webpage updates pending.</li> </ul>
Modified Simulated Voyage Requirements in Lieu of a Full Simulated Voyage for Cruise Ship Operators Repositioning to U.S. Waters and Intending to Operate with Less than 95% of Passengers Fully Vaccinated.	<ul style="list-style-type: none"> <li>• New provision aimed at reducing potential industry burden for certain operators.</li> <li>• Based on “Dear Cruise Industry Colleagues” email sent on September 21, 2021. Webpage updates pending.</li> </ul>
Applying for a COVID–19 Conditional Sailing Certificate .....	<ul style="list-style-type: none"> <li>• Shortened CDC’s time to respond to an application from 60 days to 5 days based on “Dear Cruise Industry Colleagues” letter of April 28, 2021.</li> <li>• Removed requirement for an attestation under 18 U.S.C. 1001 in line with intent to operate future program on a voluntary basis.</li> <li>• Removed requirement to submit a copy of the USCG Certificate of Inspection.</li> <li>• Removed requirement to submit proof of inspection by any other agency.</li> </ul>
Review of an Application for a COVID–19 Conditional Sailing Certificate.	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>
Amendment or Modification of COVID–19 Conditional Sailing Certificate Unchanged from original CSO.	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>
Minimum Standards for Restricted Passenger Voyages as a Condition of Obtaining and Retaining a COVID–19 Conditional Sailing Certificate.	<ul style="list-style-type: none"> <li>• Removed requirement to include any CDC travel advisory, warning, or recommendation relating to cruise travel in marketing material.</li> <li>• Removed requirement to limit voyage to 7 days.</li> <li>• Removed requirement for monitored observation period of passengers prior to embarking.</li> </ul>
Minimum Standards for Management of Passengers and Crew from COVID–19-affected Cruise Ships for Restricted Passenger Voyages.	<ul style="list-style-type: none"> <li>• Modified to state that voyage may be ended and further action taken if a ship meets “red ship criteria” under Technical Instructions for Crew.</li> <li>• Removed previous requirement that cruise ship operator must immediately end voyage, cancel future voyages, and return to port if COVID–19 identified onboard.</li> </ul>
Denials, Suspension, Revocation, and Reinstatement of a Cruise Ship Operator’s COVID–19 Conditional Sailing Certificate.	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>
Administrative review .....	<ul style="list-style-type: none"> <li>• Unchanged.</li> </ul>

**Acronyms, Initialisms, and Definitions**

(a): The acronyms and initialisms below will have the following meaning:

*ARI* means Acute Respiratory Illness defined as the presence of cough, sore throat, or runny nose (rhinorrhea) in the absence of fever and in the absence of a non-infectious diagnosis (e.g., allergies) as determined by the ship’s medical provider, or as defined by CDC in technical instructions.

*CLI* means COVID–19-like Illness.

*CDC* means U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, or an authorized representative acting on its behalf.

*EDC* means Enhanced Data Collection.

*ILI* means influenza-like illness defined as fever ( $\geq 100.4^{\circ}\text{F}$  [ $38^{\circ}\text{C}$ ]) plus either cough or sore throat or as defined by CDC in technical instructions.

(b): The terms below will have the following meaning:

*Controlled Free Pratique* has the same meaning as under 42 CFR 71.1.

*COVID–19* means the disease caused by the coronavirus SARS–CoV–2.

*COVID–19-like Illness* means ARI, ILI, pneumonia, or other signs or symptoms of COVID-like illness as defined by CDC in technical instructions.

*Crew or Crew member* means any individual serving on board a cruise

ship who is assigned to perform regular duties or tasks on behalf of a cruise ship operator in exchange for compensation.

*Cruise ship* means any commercial, non-cargo, foreign-flagged, passenger-carrying vessel operating in U.S. waters with the capacity to carry 250 or more individuals (passengers and crew), and with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.

*Cruise ship operator* means the master of the vessel (cruise ship) and any other crew member responsible for cruise ship operations and navigation, as well as any person or entity (including a

corporate entity) that authorizes or directs the use of a cruise ship (e.g., as owner, lessee, or otherwise). A cruise ship operator may also include the cruise ship captain or the cruise line to which the cruise ship belongs, and the officers and directors of the cruise line.

*Director* means the Director of the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, or an authorized representative.

*Isolation* means measures taken by a cruise ship operator to ensure the onboard or onshore separation of passengers or crew displaying signs or symptoms of COVID-19, or who have tested positive for SARS-CoV-2, from other passengers or crew who do not display such signs or symptoms or have not tested positive for SARS-CoV-2.

*Laboratory Testing or Laboratory Test Results* means testing performed in a laboratory certified as meeting the standards of the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (42 U.S.C. 263a) and 42 CFR 493 or CLIA-waived point-of-care testing or the results of such testing. Testing must be performed using tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA) as specified by CDC in technical instructions or orders.

*Operate or Operating in U.S. waters* means any action by a cruise ship operator to bring or cause a cruise ship to be brought into or transit in or between any waterways (e.g., shifting berths, moving to anchor, discharging waste, making port, or embarking or disembarking passengers or crew) subject to the jurisdiction of the United States.

*Passenger* means any individual being transported or offered transport on board a cruise ship who is not a crew member, excluding U.S. government personnel.

*Passenger operations* means any action by a cruise ship operator to cause passengers to embark or disembark a cruise ship.

*Person* means any individual or partnership, firm, company, corporation, association, organization, or other legal entity.

*Physical distancing* means maintaining a distance of at least 6 feet, or such other distance as specified by CDC in technical instructions, between one individual and another individual, not gathering in groups, and avoiding crowded places and mass gatherings.

*Quarantine* means measures taken by a cruise ship operator to ensure the onboard or onshore separation and restriction of movement of passengers or

crew who were potentially exposed to a person with COVID-19 while that person was considered infectious.

*Responsible officials* mean the Chief Executive Officer (or equivalent) of the operating cruise company and all parent companies, the Chief Compliance Officer (or equivalent) of the operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise company and all parent companies.

*Simulated voyage* means a trial voyage designed and implemented in so far as possible to replicate real world onboard conditions of cruising with measures in place to mitigate the risk of COVID-19.

*U.S. waters* means any international, interstate, or intrastate waterways that are subject to the jurisdiction of the United States.

## Background

### *Successful Resumption of Passenger Operations in Collaboration With Cruise Industry Partners*

While cruising will never be a zero-risk activity for spread of COVID-19, CDC has successfully worked with cruise ship operators to manage this risk and allow cruise ship operators to resume passenger operations in a way that mitigates the risk to crew members, passengers, port personnel, and communities. On October 30, 2020, CDC issued the CSO, which resumes cruise ship passenger operations in U.S. waters through a phased approach. There are four phases to the CSO:

- Mass crew testing and acquiring onboard laboratory testing equipment (Phase 1),
- Preparing for simulated and revenue voyages (e.g., identifying locations through port agreements to provide for the quarantine or isolation, respectively, of exposed and ill passengers) (Phase 2A) and simulated voyages to test onboard health and safety protocols (Phase 2B),
- Applying for a COVID-19 Conditional Sailing Certificate (Phase 3); and
- Restricted passenger revenue voyages with public health precautions (Phase 4).

Cruise ship operators that choose to sail with 95% vaccinated crew and 95% vaccinated passengers do not have to conduct a simulated voyage prior to applying for a COVID-19 Conditional Sailing Certificate. Cruise ships that have been operating restricted passenger voyages with 95% vaccinated crew and 95% vaccinated passengers may also transition to voyages with less than 95% vaccinated passengers by conducting

modified simulated voyage procedures in lieu of a full simulated voyage. Similarly, cruise ships that have been conducting passenger operations in non-U.S. jurisdictions and intend to operate in U.S. waters with less than 95% vaccinated passengers after repositioning to the U.S. may apply for a COVID-19 Conditional Sailing Certificate after conducting modified simulated voyage procedures instead of a full simulated voyage.

As of October 21, 2021, out of the 83 ships covered by the CSO, all have acquired the onboard laboratory testing equipment required by the CSO.<sup>11</sup> As of October 21, 2021, cruise ship operators representing 16 brands—American Queen Steamboat Company, Bahamas Paradise Cruise Line, Carnival Cruise Line, Celebrity Cruises, Crystal Cruises, Disney Cruise Line, Holland America Line, MSC Cruises, Norwegian Cruise Line, Oceania Cruises, Princess Cruises, Regent Seven Seas Cruises, Royal Caribbean International, Silversea Cruises, Ltd, Viking Cruises, and Virgin Voyages—have submitted port agreements to CDC's Maritime Unit. Additionally, CDC's Maritime Unit has been in discussions with cruise ship operators representing 2 additional brands—Azamara and ResidenSea—with specific plans to operate ships under the CSO. These port agreements collectively cover 17 primary ports of call: Cape Liberty Cruise Port (New Jersey), Port of Baltimore, Port of Boston, Port Canaveral, Port Everglades, Port of Galveston, Port of Long Beach, Port of Los Angeles, Port of Miami, Port of New Orleans, Port of New York (Manhattan), Port of Palm Beach, Port of San Diego, Port of San Francisco, Port of San Juan, Port of Seattle, and Port Tampa Bay.<sup>12 13</sup> CDC's Maritime Unit has approved port agreements for all 83 vessels covered by the CSO. Forty-eight vessels have been approved for more than one port.

<sup>11</sup>The CSO does not require cruise ships to build onboard laboratories. Rather, cruise ship operators must procure an onboard testing unit about the size of a desktop printer that easily fits within their existing medical centers. This equipment allows cruise ship operators to more easily test for the virus that causes COVID-19, can be operated with rudimentary training, and does not require a professional laboratorian. Moreover, cruise ships' pre-existing medical centers typically already have different types of laboratory testing equipment on board for diagnosing illness.

<sup>12</sup>This list represents primary ports of call (i.e., home ports) and does not include secondary ports of call, such as those in Alaska.

<sup>13</sup>Primary ports of call approved for American Queen Steamboat Company are not included in this list because their ships are U.S.-flagged and do not travel internationally. Therefore, their ships will no longer be covered under the definition of "cruise ship" in the temporary extension of the CSO.

As of October 21, 2021, CDC's Maritime Unit has received and granted 18 requests from cruise ship operators to conduct simulated voyages under the CSO. As of October 21, 2021, CDC Maritime Unit inspectors have conducted 16 onboard inspections and investigations of 15 ships, including a second inspection on a ship that transitioned from a simulated voyage to a restricted passenger voyage. These inspections ranged from one-day inspections while the ship was in port, to inspections that lasted several days while the ship was underway. Because cruise ship operators are restarting operations mostly on ships that have not carried passengers in U.S. waters since March 2020, and with new crew implementing new health and safety protocols, there may be shortfalls in training or in fully implementing protocols. However, cruise ship operators have worked closely with CDC Maritime Unit inspectors to identify and quickly remedy any observed lapses in training or protocols.

Since the issuance of the CSO in October 2020, CDC has worked collaboratively with cruise lines to ensure a safer restart of passenger operations. As of October 21, 2021, CDC's Maritime Unit has received and granted COVID-19 Conditional Sailing Certificates to conduct revenue passenger voyages to 53 ships operating under the CSO. During numerous regularly scheduled discussions, cruise industry representatives have expressed their desire to rebuild passenger confidence and prove COVID-19 can be successfully managed on board cruise ships sailing in U.S. waters. Despite the best efforts of cruise ship operators to provide a safer and healthier environment for crew and passengers, public health concerns relating to the ongoing pandemic, emergence of variants of concerns such as the Delta variant, and breakthrough infections in fully vaccinated persons highlight the need to temporarily extend the CSO, particularly as we see high levels of transmission in the United States and globally, including in countries with high rates of vaccination, such as the United Kingdom and Israel.<sup>14 15</sup>

#### Current State of COVID-19 Pandemic

As of October 21, 2021, there have been almost 241 million cases of COVID-19 globally, resulting in over 4,900,000 deaths.<sup>16</sup> Over 45 million cases have been identified in the United

States, with new cases reported daily, and over 730,000 deaths attributed to the disease.<sup>17</sup> Forecasting teams predict numbers of deaths, hospitalizations, and cases using different types of data (e.g., COVID-19 data, demographic data, mobility data), methods, and estimates of the impacts of interventions (e.g., physical distancing, use of face masks). A renewed surge in cases in the United States began in early July 2021; case counts rose from 19,000 cases per day on July 1, 2021 to over 150,000 cases per day on August 31, 2021. During the pandemic, cases have tended to surge in waves with 4 waves as of October 2021.<sup>18</sup> Therefore, additional surges of cases and deaths could be expected to occur. Similar to seasonal epidemics of influenza and other respiratory viruses, surges in cases, hospitalizations, and deaths from COVID-19 could also be expected to occur in winter as more people spend time indoors due to inclement weather.

The virus that causes COVID-19 spreads very easily and sustainably between people, particularly those who are in close contact with one another (within about 6 feet, but occasionally over longer distances). COVID-19 spreads when an infected person breathes out droplets and very small particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. Individuals without symptoms can also spread the virus. Among adults, the risk for severe illness from COVID-19 increases with age, with older adults at highest risk. Severe illness means that persons with COVID-19 may require hospitalization, intensive care, or a ventilator to help them breathe, and may be fatal. People of any age with certain underlying medical conditions (e.g., cancer, obesity, serious heart conditions, diabetes) are at increased risk for severe illness from COVID-19.<sup>19</sup>

#### Emergence of Variants

Variants of SARS-CoV-2, the virus that causes COVID-19, are expected to continue to emerge. Some will emerge and disappear, and others will emerge and continue to spread and may replace previous variants.<sup>20</sup> While it is known and expected that viruses constantly change through mutation leading to the

emergence of new variants, the Delta variant is particularly concerning because it causes more infections and spreads faster than earlier forms of SARS-CoV-2.<sup>21</sup> It has rapidly become the predominant strain in the United States, estimated to account for 99.7% of U.S. cases<sup>22</sup> and has been reported in 193 places<sup>23</sup> worldwide as of October 20, 2021.

Recent studies have also demonstrated that some fully vaccinated people exposed to the Delta variant can become infected, and those persons can be contagious and spread the illness to others, although their infectious period appears to be shorter compared to people who are not fully vaccinated.<sup>24 25 26</sup> Delta has been shown to result in higher viral loads in infected people, and spreads twice as easily from one person to another, compared to earlier strains. The ultimate concern is the emergence of a "variant of high consequence" that undermines existing public health defenses by substantially decreasing the effectiveness of available testing, treatments, and vaccines against severe or deadly disease.<sup>27</sup> 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 to arise remains a possibility.

#### Availability of Vaccines and Delta Variant

COVID-19 vaccines are now widely available in the United States, and vaccination is currently recommended for all people 12 years of age and older. As of October 21, 2021, over 189 million people in the United States (66.9% of

<sup>21</sup> 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>.

<sup>22</sup> <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>.

<sup>23</sup> <https://covid.cdc.gov/covid-data-tracker/#global-variant-report-map>.

<sup>24</sup> Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings—Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 2021;70:1059–1062. DOI: <http://dx.doi.org/10.15585/mmwr.mm7031e2>.

<sup>25</sup> Dougherty K, Mannell M, Naqvi O, Matson D, Stone J. SARS-CoV-2 B.1.617.2 (Delta) Variant COVID-19 Outbreak Associated with a Gymnastics Facility—Oklahoma, April–May 2021. MMWR Morb Mortal Wkly Rep 2021;70:1004–1007. DOI: <http://dx.doi.org/10.15585/mmwr.mm7028e2>.

<sup>26</sup> CDC: Delta Variant: What We Know about the Science.

<sup>27</sup> 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> (last updated September 23, 2021).

<sup>14</sup> <https://covid19.who.int/region/euro/country/gb>.

<sup>15</sup> <https://covid19.who.int/region/euro/country/il..>

<sup>16</sup> <https://covid19.who.int/>.

<sup>17</sup> <https://covid.cdc.gov/covid-data-tracker/#data-tracker-home>.

<sup>18</sup> <https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling.html>.

<sup>19</sup> <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

<sup>20</sup> <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern>.

the population 12 years or older) have been fully vaccinated and over 219 million people in the United States (77.4% of the population 12 years or older) have received at least one dose.<sup>28</sup>

The three COVID-19 vaccines approved or authorized in the United States are highly effective at preventing severe disease and death from COVID-19, including against the Delta variant.<sup>29 30</sup> But some fully vaccinated people will still become infected (breakthrough infection) and experience illness. While vaccination has shown to lower the risk of severe COVID-19 cases or death, people who are vaccinated and become infected with the Delta variant may still transmit the virus to others, although vaccinated people appear to be infectious for a shorter period.<sup>31 32 33 34</sup> This evidence coupled with people getting vaccinated at a slower rate in the United States, and the extreme transmissibility of the Delta variant has resulted in rapidly rising numbers of COVID-19 cases, primarily and disproportionately affecting those not fully vaccinated.

#### Justification for Temporary Extension of CSO

Despite the best efforts of cruise ship operators to provide a safer and healthier environment for crew and passengers, including operating ships with high percentages of vaccinated persons onboard, outbreaks of COVID-19 have continued to occur, many involving breakthrough infections in fully vaccinated persons. Between June 7–30, 2021, a cruise ship operator

identified 21 laboratory-confirmed COVID-19 cases onboard one of its ships, with the majority of cases among fully vaccinated persons. CDC's Maritime Unit assisted the cruise ship operator with the investigation to prevent further spread of the virus on board. In addition, the Maritime Unit collaborated with CDC's COVID-19 Laboratory Task Force to have specimens from this outbreak genetically sequenced to identify if a variant of concern was the cause. Results showed that the outbreak was in fact, due to the highly transmissible Delta variant.

As cruise ship operators continue to embark new crew in anticipation of more passenger revenue voyages in the U.S., cases of COVID-19 among crew have been reported, highlighting the continued need for public health management of cases to mitigate this risk. The resumption of passenger voyages in the U.S. has led to the introduction and sustained transmission of COVID-19 among cruise ships, despite high vaccination rates among both crew and passengers. With an increase in traveler volume, cruise ships have experienced increased numbers of COVID-19 cases among passengers and crew. Between June 26–October 21, 2021, 1,359 laboratory confirmed cases of COVID-19 were reported to CDC by cruise ships following the CSO.<sup>35</sup>

Several large outbreaks on cruise ships are highlighted below.

- On July 24, 2021, one symptomatic passenger who tested positive for COVID-19 on a cruise ship (Cruise Ship A) was epidemiologically linked to 20 additional laboratory-confirmed cases of COVID-19 over two voyages, including 2 passengers and 18 crew. The COVID-19 vaccination rate on this ship ranged between 99.8–100% for crew and 96.4–97.5% for passengers.

- Between July 24–August 28, a cruise ship (Cruise Ship B) reported 58 laboratory-confirmed COVID-19 cases among passengers and crew. The COVID-19 vaccination rate on this ship ranged between 96.8–97.7% for passengers and averaged 100% for crew.

- Between July 29–31, 2021, three symptomatic passengers tested positive for COVID-19 on a cruise ship (Cruise Ship C). Contact tracing and testing identified an additional 12 laboratory-confirmed cases of COVID-19, including 10 passengers and 2 crew. This was a highly vaccinated ship with

100% of crew and an average of 97% of passenger fully vaccinated.

- Between July 26–August 6, a cruise ship (Cruise Ship D) reported 7 laboratory-confirmed COVID-19 cases among passengers and crew. The COVID-19 vaccination rate on this ship was 100% for crew and ranged between 96.8–97.7% for passengers.

- Between August 19–September 7, a cruise ship (Cruise Ship E) reported 105 laboratory-confirmed COVID-19 cases among passengers and crew on a total of four consecutive voyages. This was a highly vaccinated ship with 100% of crew and an average of 97% of passenger fully vaccinated at the time on the voyage(s).

- Between August 21–September 7, a cruise ship (Cruise Ship F) reported a total of 112 laboratory-confirmed COVID-19 cases among passengers and crew on four consecutive voyages despite the ships' 100% vaccination rate for persons onboard.

While high vaccination rates onboard these cruise ships likely explain why onboard medical center resources have not been overwhelmed, the number of hospitalizations and medical evacuations due to COVID-19 or CLI have increased since passenger operations resumed. Between June 26–October 21, 2021, 49 hospitalizations and 38 medical evacuations for COVID-19 or CLI were reported to CDC.

Despite the implementation of strict protocols by cruise ship operators to prevent the introduction of COVID-19 from passengers, ensuring passengers are uninfected at embarkation has proven difficult. There have been several instances of passengers' being symptomatic on the day of embarkation and denying symptoms to the cruise line, or passengers' being symptomatic for several days on board the ship before reporting their symptoms to the medical center. These situations have led to complex contact tracing investigations, due to the large number of contacts exposed between presumed onset of infectiousness and when infection was identified and the passenger isolated.

For example, a passenger on a cruise ship (Cruise Ship F), who was fully vaccinated and had tested negative for COVID-19 three days before boarding, boarded the ship while symptomatic for COVID-19, but denied having symptoms. The passenger died three days after boarding for reasons related to COVID-19. This led to CDC and the cruise line taking the following public health actions:

- Contact tracing to identify exposed persons, which included interviews of passengers and crew, review of security footage, and analysis of wearable

<sup>28</sup> [https://covid.cdc.gov/covid-data-tracker/#vaccinations\\_vacc-total-admin-rate-total](https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total).

<sup>29</sup> Bernal JL, Andrews N, Gower C, et al. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. *N Engl J Med*. 2021 Jul 21;doi:10.1056/NEJMoa2108891external icon.

<sup>30</sup> Thompson MG, Burgess JL, Naleway AL, Tyner H, Yoon SK, Meece J, et al. Prevention and Attenuation of Covid-19 with the BNT162b2 and mRNA-1273 Vaccines. *N Engl J Med*. 2021;385(4):320–9.

<sup>31</sup> Mlcochova P, Kemp S, Dhar S, et al. SARS-CoV-2 B.1.617.2 Delta Variant Emergence and Vaccine Breakthrough. Research Square Platform LLC. 2021 Jun 22; doi:10.21203/rs.3.rs-637724/v1external icon.

<sup>32</sup> Musser JM, Christensen PA, Olsen RJ, et al. Delta Variants of SARS-CoV-2 Cause Significantly Increased Vaccine Breakthrough COVID-19 Cases in Houston, Texas. *medRxiv*. 2021 Jul 22; <https://org/10.1101/2021.07.07.21260122>.

<sup>33</sup> Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings—Barnstable County, Massachusetts, July 2021. *MMWR Morb Mortal Wkly Rep*. ePub: 30 July 2021; <https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm>.

<sup>34</sup> Chia PY, Ong SWX, Chiew CJ, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. 2021;doi:doi.org/10.1101/2021.07.28.21261295.

<sup>35</sup> This number does not include newly embarking crew who tested positive for SARS-CoV-2 prior to or during their embarkation quarantine period, or passengers who tested positive for SARS-CoV-2 at embarkation and did not board the ship.

technology and other relevant location data;

- Notifications to close contacts to advise them to monitor for symptoms, and to federal, state, and local partners in two states;

- Screening testing to identify those who could have been infected;
- Isolation for close contacts who tested positive for COVID-19; and
- Quarantine for close contacts who tested negative for COVID-19 but could have still developed the illness during the incubation period.

Based on these time-sensitive and labor-intensive public health actions, the cruise line identified over 30 close contacts from one infected passenger.

Cruise ship voyages from the U.S. also include itineraries to countries that have low vaccination rates but are reopening to international tourism. These countries may have limited testing capabilities for their populations, which could restrict their ability to identify COVID-19, including variants of concern. Cruise ship travel to these countries risks potentially introducing additional variants of concern into the United States. Based on CDC's assessment of risk and issuance of Travel Health Notices for international destinations,<sup>36</sup> travelers may be at increased risk for getting and spreading COVID-19 variants in the following countries where cruise ships intend to sail, per published itineraries: Aruba, the Bahamas, Barbados, Bermuda, Belize, Bonaire, Curaçao, Haiti, Honduras, Jamaica, Mexico, Saint Kitts and Nevis, Sint Maarten, and Turks and Caicos Islands.<sup>37</sup> Accordingly, based on these risks and information available to CDC, the CSO continues to represent the best way of protecting the public's health by mitigating COVID-19 transmission onboard cruise ships and into the United States.

### Findings and Immediate Action

The ongoing COVID-19 pandemic, emergence of variants of concerns, including the Delta variant, breakthrough infections in fully vaccinated persons, and possible surges of additional cases, hospitalizations, and deaths in the U.S. and in countries to which cruise ships travel support the CSO's temporary extension to mitigate

the risk of further COVID-19 introduction, transmission, and spread both onboard cruise ships and into U.S. communities.

### *Finding of Inadequate Local Control Under 42 CFR 70.2*

The cruise ships subject to this Order are all foreign-flagged and operate on international itineraries. State and local health departments consider public health on cruise ships as primarily subject to federal jurisdiction and do not routinely exercise oversight or control over cruise ship operations nor maintain maritime public health programs, particularly when such cruise ships employ mostly foreign crews and operate in international waters subject to the jurisdiction of the United States. Many state and local health departments are also currently engaged in response activities relating to the COVID-19 pandemic, and do not have the time, money, or public health resources to dedicate staff and programs to maritime public health activities. Further, based on legal authority at 42 CFR 71.31(b), CDC is the only government entity that may impose public health conditions on cruise ships operating in international waters if those ships plan to return to operating in U.S. waters. Furthermore, U.S. Coast Guard, not state and local public health departments, is the only entity that routinely conducts emergency medical evacuations at sea, including for persons with COVID-19.

Accordingly, under 42 CFR 70.2, the Director determines that based on jurisdictional limitations and other factors, the measures taken by state and local public health authorities in U.S. jurisdictions where foreign-flagged cruise ships port or travel on international itineraries and do not routinely exercise public health jurisdiction nor maintain maritime public health programs that conduct surveillance, inspections, investigations, and management for diseases of public health concern on board cruise ships have been and are insufficient to prevent the spread of COVID-19 into and among U.S. states and territories.<sup>38</sup>

<sup>38</sup> These jurisdictions include the following U.S. states: Alabama, Alaska, California, Delaware, Florida, Georgia, Hawaii, Illinois, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, Texas, Virginia, and Washington State. These jurisdictions also include the following U.S. territories: American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands. CDC is not currently aware of any states or U.S. territories operating a maritime public health program that would displace the CSO.

### *Statement of Good Cause Under the Administrative Procedure Act ("APA")*

COVID-19 cases, hospitalizations, and deaths continue to increase, especially in areas with higher levels of community transmission and lower vaccination coverage.<sup>39</sup> Furthermore, while pediatric cases and hospitalizations have decreased in recent weeks following a previous increase, cases and hospitalizations could surge again.<sup>40</sup> Based on the rapidly increasing cases and spread of the Delta variant and other variants of SARS-CoV-2, and to reduce introduction and spread of these and future SARS-CoV-2 variants into the United States, including a potential variant of high consequence, at a time when cruise ship travel has resumed, CDC must take quick and targeted action to further curtail the spread of Delta and other new virus variants into the United States.

The Director continues to find evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease.<sup>41</sup> This reasonable belief is based on information from epidemiologic and other data.<sup>42</sup> As a result, absent measures of the type specified in the

<sup>39</sup> <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

<sup>40</sup> <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

<sup>41</sup> The list of federally quarantinable communicable diseases as defined by Executive Order includes severe acute respiratory syndromes, defined as diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This definition does not apply to influenza. See Executive Order 13295 (April 4, 2003), as amended by Executive Orders 13375 (April 1, 2005), 13674 (July 31, 2014), and 14047 (September 17, 2021). CDC has determined that COVID-19 meets the definition of a severe acute respiratory syndrome and therefore is a quarantinable communicable disease.

<sup>42</sup> Multiple studies have confirmed that COVID-19 transmission rates onboard cruise ships are higher than in other settings. Kordsmeyer, A.-C.; Mojtahedzadeh, N.; Heidrich, J.; Militzer, K.; von Münster, T.; Belz, L.; Jensen, H.-J.; Bakir, S.; Henning, E.; Heuser, J.; et al. *Systematic Review on Outbreaks of SARS-CoV-2 on Cruise, Navy and Cargo Ships*. Int. J. Environ. Res. Public Health 2021, 18, 5195. <https://doi.org/10.3390/ijerph18105195>; Rocklöv J, Sjödin H, Wilder-Smith A. *COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures*. J. Travel Med. 2020; 18:27(3): taaa030. <https://doi.org/10.1093/jtm/taaa030>; Payne DC, Smith-Jeffcoat SE, Nowak G, et al. *SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members—USS Theodore Roosevelt*. April 2020. MMWR Morb Mortal Wkly Rep 2020;69:714–721. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e4>.

<sup>36</sup> How CDC Determines the Level for COVID-19 Travel Health Notices.

<sup>37</sup> COVID-19 in Aruba, COVID-19 in the Bahamas, COVID-19 in Barbados, COVID-19 in Belize, COVID-19 in Bermuda, COVID-19 in Bonaire, COVID-19 in Curaçao, COVID-19 in Haiti, COVID-19 in Honduras, COVID-19 in Jamaica, COVID-19 in Mexico, COVID-19 in Saint Kitts and Nevis, COVID-19 in Sint Maarten, COVID-19 in Trinidad and Tobago, and COVID-19 in the Turks and Caicos Islands.

CSO, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to the virus that causes COVID-19 by virtue of being on board at a time when the virus, including the highly transmissible Delta variant, continues to circulate globally and in the U.S. Additionally, persons infected on cruise ships would be likely to transmit COVID-19 to U.S. communities by traveling interstate after disembarking a cruise ship.

This Order is not a rule within the meaning of the Administrative Procedure Act (“APA”), but rather an emergency action taken under the existing authority of 42 CFR 70.2, 71.31(b), and 71.32(b). If this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because good cause exists to dispense with prior public notice and the opportunity to further comment on this Order. Considering the public health emergency caused by COVID-19, including the Delta variant, based on, among other things, its potential for spread on board cruise ships and potential to cause breakthrough infections in vaccinated persons, 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. 5 U.S.C. 553(b)(B), (d)(3).

Similarly, if this Order qualifies as a rule per the definition in the APA, the Office of Information and Regulatory Affairs has determined that it would be a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121, SBREFA), 5 U.S.C. 804(2), but there would not be a delay in its effective date under 5 U.S.C. 808(2) as the agency has invoked the good cause provision of the APA. As explained in this Order, during the pandemic, cases have tended to surge in waves with 4 waves as of October 2021.<sup>43</sup> Therefore, additional surges of cases and deaths can be expected. The winter season (November through January) has historically been the most active cruising season in the Caribbean and Central America, involving travel to countries currently listed by CDC as being under COVID-19 travel health notices where cruise ship travelers may be at increased risk for acquiring and subsequently introducing COVID-19 variants into the U.S. Additionally, cruise ship operators have informed CDC of their intended plans to increase the number of ships operating

in U.S. waters this fall and winter. Accordingly, in light of the rapidly evolving public health situation and expected increase in winter cruising activity, pausing the operation and enforcement of the CSO to allow for a notice and comment period would be impracticable and contrary to the public interest.

While it was not feasible based on the rapidly evolving pandemic and emergence of variants of concern to seek full notice and comment through rulemaking, CDC solicited specific feedback from cruise ship operators and other partners relating to the measures in this temporary CSO extension. Unfortunately, CDC received low response rate to its solicitation (n=15). Almost three quarters of the respondents were cruise industry representatives (n=11) and the responses may have underrepresented non-cruise stakeholder partners (such as state and local health departments, seaport partners, and U.S. government interagency partners). Therefore, CDC acknowledges that further solicitation and feedback are warranted before existing elements of the CSO are maintained, modified, or rescinded as part of any future voluntary program.

Based on feedback received, the majority of respondents agreed on the importance of COVID-19 industry-wide standards including:

- Surveillance protocols,
- medical protocols, capabilities, and supplies for managing patients on board, and
- preventive measures & public health interventions (e.g., mask use, physical distancing, cleaning and disinfection, infection prevention and control plans).

The majority of respondents also agreed on the importance of continued communication and close collaboration between CDC and cruise lines, including through regularly scheduled executive session calls between cruise lines, CDC, and interagency representatives to exchange information and share ideas; regularly scheduled technical assistance calls between CDC’s Maritime Unit and cruise lines’ public health personnel; and ad hoc outbreak assistance calls between CDC’s Maritime Unit and cruise lines’ medical and public health staff.

While most cruise industry respondents disagreed that port agreements were useful for the resumption of passenger operations, respondents were divided as to whether individual components of the port agreements (e.g., medical care, housing, and vaccination) were important for future cruise operations. However,

based on previous feedback from state and local health departments and seaport partners, CDC believes that emergency response planning is an important element of COVID-19 health and safety protocols that should be a part of future cruise ship operations. The exact elements of such emergency response planning would be the subject of further discussion and information sharing as part of any future voluntary program between CDC and the cruise ship industry.

Most cruise industry respondents also disagreed that CDC’s Cruise Ship Color Status web page was useful for communicating information about COVID-19 on cruise ships in U.S. jurisdictions. However, CDC believes it is important to be transparent and continue to advise the public about COVID-19 conditions on board cruise ships so that passengers can make better informed decisions based on their preexisting medical conditions and risk of severe illness. How best to inform the public about COVID-19 conditions on board cruise ships would similarly be the subject of further discussion and information sharing as it relates to any future voluntary program.

The interest of cruise ship operators in participating in a future voluntary program to detect, mitigate, and control the spread of COVID-19 during future cruise ship operations is also difficult to gauge based on this limited initial feedback. Of the 11 cruise industry respondents, 4 indicated they would be interested in such a program and 7 indicated that they would not be. Based on written comments received to this question, some cruise ship operators expressed reticence to respond in the affirmative in the absence of additional details regarding the scope and parameters of such a voluntary program. Regardless, CDC wishes to stress that cruise ship participation in any future voluntary program would not be mandated; the scope and parameters of such a program would be subject to further discussion and information sharing; and cruise ship operators would be free to develop alternative pathways of detecting, mitigating, and controlling the spread of COVID-19 onboard cruise ships.

Accordingly, CDC will use the additional time provided by this temporary extension to better gauge interest in a voluntary program and continue to explore alternative pathways to detect, mitigate, and control the spread of COVID-19 onboard cruise ships. During this temporary extension period, CDC intends to solicit additional feedback from the cruise industry, state and local

<sup>43</sup> <https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling.html>.

health departments, seaport partners, and U.S. government interagency partners as may be needed to explore interest in and develop a voluntary program to assist the cruise ship industry to detect, mitigate, and control the spread of COVID-19 onboard cruise ships for those cruise ship operators who may wish to be involved in such a program.

#### *Severability of Provisions*

If any provision in this 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.

#### *Federal Preemption*

In accordance with 42 U.S.C. 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that conflict with an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

#### *Enforceability*

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 70.18, 71.2. While this Order may be enforced and CDC reserves the right to enforce in appropriate circumstances through criminal penalties, CDC does not intend to rely primarily on these criminal penalties but instead anticipates continued widespread voluntary compliance from cruise ship operators as well as support from U.S. Coast Guard.

Therefore, in accordance with sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.31(b), 71.32(b), for all cruise ships as defined in this Order for the period described below, it is ordered:

#### **Framework for Conditional Sailing Order**

##### *Purpose and Scope*

(a) *Purpose.* The purpose of this framework is to prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States via cruise ships. These requirements are in addition to other requirements in regulations or actions taken by HHS/CDC to prevent the introduction, transmission, and spread

of communicable diseases under 42 U.S.C. 264 and 42 CFR part 70 and 42 CFR part 71.

(b) *Scope.* This framework applies to any person operating or intending to operate a foreign-flagged cruise ship in U.S. waters and to any person operating a foreign-flagged cruise ship outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters while this Order remains in effect.

(1) Upon request, cruise ship operators must make their properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records.

(2) CDC may enforce any of the provisions of this framework through additional orders published in the **Federal Register** and issue additional technical instructions as needed.

(3) Nothing in this framework supersedes or preempts enforcement of emergency response requirements imposed by statutes or other regulations.

#### *General Prohibition on a Cruise Ship Operator Commencing or Continuing Passenger Operations Without a COVID-19 Conditional Sailing Certificate*

(a) A cruise ship operator subject to this Order must meet the requirements of this framework as a condition of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters or if the cruise ship operator is operating a cruise ship outside of U.S. waters and intends for the ship to return to operating in U.S. waters while this Order remains in effect. These requirements must additionally be met as a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or applying for a COVID-19 Conditional Sailing Certificate.

(b) A cruise ship operator shall not commence or continue any passenger operations in U.S. waters without a COVID-19 Conditional Sailing Certificate issued by CDC that meets the requirements in this framework for each cruise ship that the cruise ship operator intends to operate with passengers in U.S. waters.

(c) A cruise ship operator shall not violate the terms or conditions of a COVID-19 Conditional Sailing Certificate issued pursuant to this framework.

(d) As a condition of obtaining or retaining a COVID-19 Conditional

Sailing Certificate, the cruise ship operator must be in compliance with CDC's standards for mitigating the risk of COVID-19 onboard the cruise ship as set forth in this framework and in CDC technical instructions or orders.

#### *Requirements for COVID-19 Response Plan for Cruise Ship Operators Operating or Intending To Operate Cruise Ships in U.S. Waters*<sup>44</sup>

(a) Cruise ships operating or intending to operate in U.S. waters must have a COVID-19 response plan that includes the following components:

(1) Terminology and use of definitions that align with how CDC uses and defines the following terms: "confirmed COVID-19," "COVID-19-like illness," "close contact," "fully vaccinated for COVID-19," and "isolation" and "quarantine" (including timeframes for isolation and quarantine).

(2) Protocols for on board surveillance of passengers and crew with COVID-19 and COVID-19-like-illness.

(3) Protocols for training all crew on COVID-19 prevention, mitigation, and response activities.

(4) Protocols for on board isolation and quarantine, including how to increase capacity in case of an outbreak.

(5) Protocols for COVID-19 testing that aligns with CDC technical instructions.

(6) Protocols for onboard medical staffing—including number and type of staff—and equipment in sufficient quantity to provide a hospital level of care (e.g., ventilators, face masks, personal protective equipment) for the infected without the immediate need to rely on shoreside hospitalization.

(7) Procedures for disembarkation of passengers who test positive for COVID-19.

(b) The cruise ship operator has observed and will continue to observe all elements of its COVID-19 response plan including following the most current CDC recommendations and guidance for any public health actions related to COVID-19.

<sup>44</sup> COVID-19 response plans were formerly referred to as "No Sail Order" response plans. Cruise ship operators that previously submitted a signed "Acknowledgment of No Sail Order Response Plan Completeness and Accuracy" to CDC have fulfilled the requirements of this section and do not need to re-submit a COVID-19 response plan.

*Requirements for COVID-19 Testing Capabilities and Reporting for Cruise Ship Operators Operating or Intending To Operate Cruise Ships in U.S. Waters*<sup>45</sup>

(a) Cruise ships operating or intending to operate in U.S. waters must have onboard testing capabilities as directed by CDC in technical instructions or orders to test all symptomatic crew and passengers for COVID-19 and their close contacts. These capabilities include having onboard rapid nucleic acid amplification test (NAAT) point-of-care equipment that meets the requirements specified by CDC in technical instructions or orders.<sup>46</sup> This testing instrument must be authorized by FDA for use in a CLIA-waived setting, have been evaluated on the FDA reference panel for SARS-CoV-2,<sup>47</sup> allow for specimen-to-instrument transfer in a way that minimizes the risk of contamination, and possess a limit of detection (LoD) value  $\leq 18,000$  NDU/ml.

(b) Cruise ships operating in U.S. waters must continue to submit the EDC form as specified in CDC technical instructions or orders. Cruise ship operators with ships that have not been in U.S. waters during the period of the CSO and who wish to operate those ships in U.S. waters during the period that this framework remains in effect, must additionally submit the EDC form during (at a minimum) the 14 days preceding those ships' expected arrival in U.S. waters and continue to submit the EDC form after the ships' entering U.S. waters or, alternatively, arrange for such appropriate shoreside or ship-based testing of passengers and crew as directed by CDC with subsequent submission of the EDC form after the ships' arrival.

(c) The cruise ship operator has arranged for and submitted and will continue to arrange for and submit such COVID-19 test results as may be required by CDC for every crew member on board ships operating in U.S. waters and/or operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while this Order

<sup>45</sup> This section does not impose new requirements on cruise ship operators but merely restates requirements that cruise ship operators previously fulfilled during Phase 1 of the CSO. These requirements were previously published under the section "Requirements for Protection of Crew for Cruise Ship Operators Operating or Intending to Operate Cruise Ships in U.S. Waters."

<sup>46</sup> Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew | Quarantine | CDC.

<sup>47</sup> For tests that do not have the FDA reference panel available, tests will be accepted using sensitivity data  $\geq 95\%$  from clinical samples as indicated in the manufacturer's instructions for use.

remains in effect. Routine COVID-19 screening testing of all crew must be conducted at such other intervals as required by CDC in technical instructions or orders. CDC may conduct oversight of specimen collection, testing, and laboratory procedures, as necessary.

(d) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for protection of crew.

*Agreement With Port and Local Health Authorities*<sup>48</sup>

(a) As a condition of obtaining or retaining controlled free pratique for conducting a simulated voyage or obtaining and retaining a COVID-19 Conditional Sailing Certificate, a cruise ship operator must document the approval of all U.S. port and local health authorities where the ship intends to dock or make port during a simulated voyage or a restricted passenger voyage. Such written approval must include the following:

(1) A medical care agreement between the cruise ship operator and health care entities, addressing evacuation to onshore hospitals for passengers and crew in need of care, in accordance with CDC technical instructions and orders.<sup>49</sup>

(2) A housing agreement between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of COVID-19 cases and close contacts, respectively, identified from the day of embarkation through disembarkation for each voyage, in accordance with CDC technical instructions and orders.

(3) A port agreement between the cruise ship operator and port authority that takes into consideration the public health response resources of the jurisdiction in the event of a COVID-19 outbreak, a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, and vaccination strategies to maximally protect passengers and crew from introduction, amplification, and spread of COVID-19 in the maritime environment and in land-based communities.

(b) In lieu of documenting the approval of all local health authorities of jurisdiction, the cruise ship operator may instead submit to CDC a signed

<sup>48</sup> Cruise ship operators that previously submitted and had their port and local health agreements accepted by CDC are not required to take any further action under this section if such agreements continue to remain in effect.

<sup>49</sup> <https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html>.

statement from a local health authority, on the health authority's official letterhead, indicating that the health authority has declined to participate in deliberations and/or sign the port agreement, *i.e.*, a "Statement of Non-Participation."

(c) In documenting the approval of all U.S. port and local health authorities where the ship intends to dock or make port during simulated voyages or restricted passenger voyages, the cruise ship operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement.

*Minimum Standards for Simulated Voyages Prior to Issuance of COVID-19 Conditional Sailing Certificate*

(a) As a condition of applying for a COVID-19 Conditional Sailing Certificate, a cruise ship operator must have successfully conducted a simulated voyage demonstrating the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship. A simulated voyage must meet the following requirements:<sup>50</sup>

(1) The cruise ship operator must inform volunteer passengers in writing that they are participating in a simulation of health and safety protocols for purposes of simulating a cruise ship voyage.

(2) All volunteer passengers must be at least twelve years old or older. The cruise ship operator must also obtain from all volunteer passengers a written certification from a healthcare provider that the volunteer passenger has no pre-existing medical conditions that would place that individual at high risk for COVID-19 as determined through CDC guidance. CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's obligation to screen for volunteer passengers who may be at high risk for COVID-19.

(3) The cruise ship operator must conduct any simulation on a consensual basis. The cruise ship operator must document the informed consent of all adult participants in writing. If any minors are to participate in the simulation then the informed consent of a parent or guardian, and the written assent of the minor must also be documented in writing. All persons younger than eighteen years old must be fully vaccinated against COVID-19 as a

<sup>50</sup> <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>.

condition of participation on a simulated voyage.

(4) The cruise ship operator must design and conduct a simulated voyage insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship.

(5) The cruise ship operator must conduct laboratory testing of volunteer passengers, as directed in CDC technical instructions or orders, prior to embarking volunteer passengers on a simulated voyage.

(6) A simulated voyage must include the following simulated activities:

- (i) Embarkation and disembarkation procedures, including terminal check-in,
- (ii) on board activities, including at dining and entertainment venues,
- (iii) private island shore excursions, if any are planned during restricted passenger voyages,
- (iv) evacuation procedures,
- (v) transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms,
- (vi) quarantine of all remaining passengers and non-essential crew, and
- (vii) other activities as may be listed in CDC technical instructions and orders.

(7) The cruise ship operator must meet standards for hand hygiene, facemasks, and physical distancing for passengers and crew, as well as ship sanitation, as may be required by CDC technical instructions or orders.

(8) The cruise ship operator must modify meal service and entertainment venues to facilitate physical distancing during the simulated voyage.

(9) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation as required by CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking and prior to passengers and crew departing for their final destinations after disembarking the ship. Crew and passengers must also be laboratory tested again post-disembarkation as required by CDC technical instructions or orders. Based on public health considerations, CDC may also require additional laboratory testing of passengers and crew and reporting of results, including during a voyage, as required by CDC technical instructions or orders.

(10) The cruise ship operator must immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19

during the simulated voyage with rapid point-of-care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point-of-care results.

(11) CDC may require the cruise ship operator to immediately end the simulated voyage and take other action to protect the health and safety of volunteer passengers and crew if during the simulation a threshold of COVID-19 cases, as determined by CDC in technical instructions, is met or exceeded.<sup>51</sup>

(12) The cruise ship operator must document any deficiencies in its health and safety protocols through an "after-action" report and address how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. This after-action report must also include test results for any volunteer passengers or crew on the simulated voyage. The after-action report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate.

(13) Based on CDC's review of the after-action report and/or cruise ship operator's application for a COVID-19 Conditional Sailing Certificate, CDC may require that the cruise ship operator modify its practices or procedures prior to the issuance of the COVID-19 Conditional Sailing Certificate.

(b) Prior to conducting a simulated voyage in accordance with this section, the cruise ship operator must provide written notice and request CDC's approval to conduct the simulation. Such written notice must be provided prior to the simulation and specify the time, location, contact information for all individuals or parties involved, and protocols or practices to be simulated. This written notice must be submitted at least 5 business days prior to the date on which the cruise ship operator proposes to conduct the simulation.

(c) A cruise ship operator shall not apply for approval to conduct a

simulated voyage until all of CDC's requirements relating to onboard laboratory capacity and screening testing of crew in U.S. waters have been satisfied. The cruise ship operator's responsible officials must sign the application for permission to conduct a simulation and certify that all of CDC's requirements relating to onboard point-of-care laboratory capabilities and screening testing of crew onboard cruise ships in U.S. waters have been satisfied.

(d) CDC will respond to the written notice and request for approval to conduct a simulation in writing in a timely manner. CDC may deny the request to conduct a simulation if the cruise ship operator is not in compliance with any provision of this framework, technical instructions, or orders, or if in CDC's determination the simulation does not provide adequate safeguards to minimize the risk of COVID-19 for all participants.

(e) CDC may conduct such oversight and inspection of simulated voyages as it deems necessary in its discretion, including through in-person or remote means allowing for visual observation.

(f) CDC may issue additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures for conducting and evaluating a simulated voyage prior to applying for a COVID-19 Conditional Sailing Certificate.

(g) In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an acknowledgement that 95% of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95% of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

(h) In lieu of conducting a simulated voyage under this paragraph, cruise ship operators, at their discretion, may choose to follow the procedures for modified simulated voyages if transitioning to voyages with less than 95% of passengers fully vaccinated or if operating cruise ships outside of U.S. waters and intending to operate with less than 95% of passengers fully vaccinated after repositioning to U.S. waters.

*Procedures in Lieu of Conducting a Simulated Voyage for Cruise Ship Operators Transitioning to Voyages With Less Than 95% of Passengers Fully Vaccinated*

(a) Cruise ships that have been operating restricted passenger voyages

<sup>51</sup> During simulated passenger voyages, this threshold is currently met when 1.5% of COVID-19 cases is detected in passengers or 1.0% of COVID-19 cases is detected in crew. This threshold may be modified based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors. If a simulated voyage is ended early to protect health and safety, CDC will consult with the cruise ship operator regarding any deficiencies to be noted in the operator's after-action report and how such deficiencies are to be corrected prior to approving an application for a COVID-19 Conditional Sailing Certificate.

under an acknowledgement by the cruise ship operator's responsible officials that they will only operate with 95% of crew (excluding any newly embarking crew in quarantine) and 95% of passengers who are fully vaccinated may, at their discretion, transition to operating restricted passenger voyages with less than 95% of passengers fully vaccinated without first conducting a simulated voyage if the following are met:

(1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%.

(2) The ship must have operated on restricted passenger voyages under an acknowledgement by the cruise ship operator's responsible officials that they will only operate with 95% of crew (excluding any newly embarking crew in quarantine) and 95% of passengers who are fully vaccinated for at least 60 days.

(3) At least 14 days prior to the transition to voyages with less than 95% of passengers fully vaccinated, the cruise ship operator must submit the following to CDC:

(i) Protocols for how dining and entertainment venues, and recreational activities including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will be modified to incorporate mask use, physical distancing, and other public health measures as outlined in CDC technical instructions.<sup>52</sup>

(ii) Plans for training crew on new procedures for mask use, physical distancing, and other public health measures as outlined in CDC technical instructions.

(iii) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical personnel) as determined by the cruise ship operator and as needed in the event of an outbreak.

(iv) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated.

(v) Procedures for notifying passengers who booked a 95% passenger vaccinated cruise that their cruise will no longer operate as a 95% passenger vaccinated cruise.

(vi) The cruise ship operator must submit photographs or videos, no later

than 7 days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools.

*Modified Simulated Voyage Requirements in Lieu of a Full Simulated Voyage for Cruise Ship Operators Repositioning to U.S. Waters and Intending To Operate With Less Than 95% of Passengers Fully Vaccinated*

(a) Cruise ship operators that have been conducting passenger operations outside of U.S. waters and intend to operate cruise ships with less than 95% of passengers fully vaccinated after repositioning to U.S. waters may, at their discretion, follow the procedures in this paragraph for conducting a modified simulated voyage instead of conducting a full simulated voyage if the following are met:

(1) The ship must maintain a percentage of fully vaccinated crew that is greater than or equal to 95%.

(2) The ship must have operated with passengers outside of U.S. waters for at least 60 days before entering U.S. waters.

(3) The cruise ship operator must conduct at least one simulation of embarkation screening and testing at the port terminal it intends to use in the U.S.—to include the number of passengers not fully vaccinated expected on the first voyage—unless the ship will be operating at the terminal already in use by the same cruise line/brand for passenger operations.

(4) At least 14 days prior to entering U.S. waters, the cruise ship operator must submit the following to CDC:

(i) Protocols for how dining and entertainment venues, and recreational activities, including buffets, seated dining, bars (including between bartenders and patrons), theaters, other performance venues, casinos, arcade room, spa services, fitness classes/gymnasiums, muster drills, and other areas where passengers congregate will incorporate mask use, physical distancing, and other public health measures as outlined in technical instructions.

(ii) Plans for training crew on procedures for mask use, physical distancing, and other public health measures as outlined in CDC technical instructions.

(iii) Protocols for increasing the number of isolation and quarantine cabins and on-board support staff (e.g., administrative personnel, testing personnel, contact tracers, medical

personnel) as determined by the cruise ship operator and as needed in the event an outbreak.

(iv) Procedures for how crew will identify and distinguish between passengers who are fully vaccinated and passengers who are not fully vaccinated.

(v) Procedures for notifying passengers who booked a 95% vaccinated cruise that their cruise will no longer operate as a 95% vaccinated cruise, if applicable.

(vi) An after-action report explaining lessons learned from sailing outside of U.S. waters and from the simulated embarkation screening and testing (if such a simulation was conducted).

(vii) The cruise ship operator must submit photographs or videos, no later than 7 days after commencing the first voyage with less than 95% of passengers fully vaccinated, showing compliance with indoor mask use and physical distancing, such as signage in elevators, dining table arrangements, and blocking out seats/bar stools.

*Applying for a COVID-19 Conditional Sailing Certificate*<sup>53</sup>

(a) A cruise ship operator must submit the following to CDC at least 5 business days prior to the date on which the cruise ship operator proposes to commence restricted passenger operations:

(1) A completed CDC registration/application form that includes the signatures of the cruise ship operator's responsible officials.

(2) The name, titles, and contact information for the cruise ship operator's responsible officials.

(3) A completed statement of intent stating the name, carrying capacity for passengers and crew, itinerary, ports of call, length of voyage, and expected onboard or shoreside activities, for the cruise ship that the cruise ship operator intends to have certified for restricted passenger operations.

(4) A certification statement signed by the responsible officials acknowledging that the cruise ship operator has complied and remains in compliance with CDC's requirements for a COVID-19 Response Plan and EDC reporting prior to applying for a COVID-19 Conditional Sailing Certificate.

(5) A certification statement signed by the responsible officials acknowledging that the cruise ship operator has adopted health and safety protocols that meet CDC's standards for mitigating the risk of COVID-19 among passengers and

<sup>52</sup> COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order | Quarantine | CDC.

<sup>53</sup> Cruise ship operators who have previously submitted and received a COVID-19 Conditional Sailing Certificate are not required to take any further action under this section.

crew onboard the cruise ship that will be commencing restricted passenger operations and will modify these protocols as needed to protect the public's health as required by CDC technical instructions or orders.

(6) A certification statement signed by the responsible officials acknowledging that the cruise ship operator has sufficient medical and point-of-care laboratory capabilities and staff on board the cruise ship that will be commencing restricted passenger operations to manage severe COVID-19 cases and outbreaks in exigent circumstances as required by CDC technical instructions or orders.

(7) A certification statement signed by the responsible officials acknowledging that the cruise ship operator is in compliance with the other requirements contained in this framework for mitigating the risk of COVID-19 on board cruise ships and agrees to continue to comply with these requirements.

#### *Review of an Application for a COVID-19 Conditional Sailing Certificate*

(a) Upon receiving the documentation required by this framework, CDC will review the application for completeness. Based on CDC's determination as to whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID-19 onboard the cruise ship for which the operator intends to commence restricted passenger operations, it shall grant or deny the application. If CDC requires additional information to ascertain whether the cruise ship operator has met CDC's standards for mitigating the risk of COVID-19 on board cruise ships, or if it determines the application to be incomplete, it may hold the application in abeyance, or in its discretion provisionally grant the application, pending the submission of such additional information as required by CDC to make such a determination. Applications that are denied may be administratively appealed as described in this framework.

(b) CDC may limit the terms or conditions of a cruise ship operator's COVID-19 Conditional Sailing Certificate in regard to passenger or crew capacity, itinerary, ports of call, length of voyage, onboard or shoreside activities, or in regard to any other passenger, crew, or cruise ship operations, as needed to the health and safety of passengers and crew or the public's health.

(c) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, the cruise ship operator must upon request make its

properties and records available for inspection to allow CDC to ascertain compliance with this framework. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records. The cruise ship operator must also make any crew member or other personnel involved in the operation of a cruise ship available for interview by CDC.

(d) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, cruise ship operators must establish mechanisms to ensure compliance, including reporting mechanisms to notify CDC and U.S. Coast Guard in writing within 24 hours of the occurrence of any deviations, whether intentional, or as a result of error or omission, and take corrective steps to rectify those deviations.

(e) As a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate, cruise ship operators must comply with the requirements of this framework. These requirements apply to any cruise ship operating in U.S. waters and to cruise ships operating outside of U.S. waters if the cruise ship operator intends for the ship to return to operating in U.S. waters at any time while Order remains in effect.

#### *Amendment or Modification of COVID-19 Conditional Sailing Certificate*

(a) A cruise ship operator may seek to amend or modify a COVID-19 Conditional Sailing Certificate issued under this framework by submitting such amendment or modification to CDC for review and a determination in accordance with this section.

(b) CDC will review the cruise ship operator's request to amend or modify a COVID-19 Conditional Sailing Certificate and either grant or deny the request in writing. If CDC requires additional information to ascertain whether the cruise ship operator's proposed amendment or modification meets CDC's standards for mitigating the risk of COVID-19 on board cruise ships, or if it determines the request to be incomplete, it may hold the request in abeyance, or in its discretion provisionally grant the application, pending the submission of such additional information as required by CDC to make such a determination.

(c) CDC may require any cruise ship operator to amend or modify a COVID-19 Conditional Sailing Certificate based on public health considerations specific to the cruise ship, cruise ship operator, or affecting the health or safety of cruise travel as a whole.

(d) Denials of requests to amend or modify a COVID-19 Conditional Sailing Certificate are subject to administrative review as described in this framework.

#### *Minimum Standards for Restricted Passenger Voyages as a Condition of Obtaining and Retaining a COVID-19 Conditional Sailing Certificate*

(a) As a condition of obtaining and retaining a COVID-19 Conditional Sailing Certificate, a cruise ship operator must meet the following minimum standards:

(1) The cruise ship operator must screen passengers and crew before they embark for signs and symptoms or known exposure to COVID-19 and deny boarding to anyone who is suspected of having COVID-19 or is an identified contact of a confirmed or suspected case, in accordance with CDC technical instructions or orders.<sup>54 55</sup>

(2) The cruise ship operator must conduct laboratory testing of all passengers and crew on the day of embarkation and the day of disembarkation in accordance with CDC technical instructions or orders. Laboratory test results must be available prior to passengers embarking and prior to passengers and crew departing for their final destinations after disembarking the ship.

(3) The cruise ship operator must immediately conduct laboratory testing of any passengers and crew who report illness consistent with COVID-19 during the voyage with rapid point-of-care results as required by CDC technical instructions or orders. Identified close contacts of cases must also be laboratory tested with rapid point-of-care results.

(4) The cruise ship operator must report syndromic surveillance and all laboratory test results using CDC's EDC form as required by CDC technical instructions or orders.

(5) The cruise ship operator must meet standards for hand hygiene, face masks, and physical distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.

(6) The cruise ship operator must modify meal service and entertainment venues to facilitate physical distancing as required by CDC technical instructions or orders.

(b) In light of public health considerations and based on evidence gained through review and evaluation of

<sup>54</sup> COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order | Quarantine | CDC.

<sup>55</sup> Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew | Quarantine | CDC.

cruise operators' practices and procedures, including through simulated voyages, CDC may require the following:

(1) Post-day of disembarkation laboratory testing of passengers and crew.

(2) Additional laboratory testing of passengers and crew and reporting of results during a voyage.

(c) CDC may issue additional technical instructions or orders regarding health and safety standards for restricted passenger voyages.

*Minimum Standards for Management of Passengers and Crew From COVID-19-Affected Cruise Ships for Restricted Passenger Voyages*

(a) Based on COVID-19 being detected in passengers or crew, as determined through CDC technical instructions or orders, a cruise ship operator must immediately take the following actions:

(1) Conduct such notifications of passengers, crew members, and other government entities as CDC may require.

(2) Immediately isolate any sick or infected passengers and crew in single occupancy cabins with private bathrooms and quarantine all remaining passengers and non-essential crew.

(3) Disembark and evacuate passengers and crew only in such a manner as prescribed in the cruise ship operator's preexisting port and local health authority agreements.

(4) Arrange to disembark and transport passengers and crew using noncommercial transportation or other transportation in accordance with CDC's technical instructions and orders.

(5) Instruct disembarking passengers and crew to stay home and continue to practice physical distancing after reaching their final destination as per CDC technical instructions or orders.

(6) Inform ship pilots, ground transportation, aircraft operators, and other agencies with relevant jurisdiction that COVID-19 has been detected in passengers or crew and confirm that the operators have plans in place to notify and protect the health and safety of their staff (e.g., drivers, air crews).

(7) If the ship meets the red ship criteria,<sup>56</sup> immediately end the restricted passenger voyage, cancel future restricted passenger voyages until

<sup>56</sup> A ship will be considered as meeting red ship criteria if the ship has sustained transmission of COVID-19 or CLI, or potential for COVID-19 cases to overwhelm on board medical center resources. CDC may adjust these criteria based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors.

directed by CDC that such voyages may resume, and return the ship to the U.S. port of embarkation.

(b) CDC may issue additional technical instructions or orders regarding what measures cruise ship operators must take in the event that a threshold of COVID-19 cases is detected in passengers or crew.

*Denials, Suspension, Revocation, and Reinstatement of a Cruise Ship Operator's COVID-19 Conditional Sailing Certificate*

(a) CDC may deny an application for a COVID-19 Conditional Sailing Certificate, or revoke, or suspend a COVID-19 Conditional Sailing Certificate if:

(1) The cruise ship operator is not in compliance with CDC's standards for mitigating the risk of COVID-19 on board cruise ships; or

(2) the cruise ship operator is not in compliance with the terms of its COVID-19 Conditional Sailing Certificate; or

(3) necessary to protect human health or safety based on public health considerations specific to the particular cruise ship operator, cruise ship, or affecting cruise travel as a whole.

(b) CDC may reinstate a suspended or revoked COVID-19 Conditional Sailing Certificate after:

(1) Inspecting the cruise ship operator's properties and records, including, but are not limited to, its vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health records;

(2) conferring with the cruise ship operator, responsible officials, or other persons under the cruise ship operator's employ; and

(3) receiving information and written assurances from the cruise ship operator and/or its responsible officials that any deficiencies have been rectified and actions taken to ensure future compliance.

*Administrative Review*

(a) A cruise ship operator may appeal a denial of its application for a COVID-19 Conditional Sailing Certificate or a revocation or suspension of its COVID-19 Conditional Sailing Certificate based on specific factors particular to that operator.

(b) The cruise ship operator's appeal must be in writing, state the factual basis for the appeal, and be submitted to the CDC Director within 30 calendar days of the decision.

(c) The CDC Director's decision will be issued in writing and will constitute final agency action. Prior to deciding

upon an appeal, the Director may further investigate the reasons for the denial, revocation, or suspension, including by conferring with the cruise ship operator, responsible officials, or other persons under the cruise ship operator's employ.

This Order enters into effect on November 1, 2021 at 12:01 a.m. (EDT) upon the expiration of the current Order. While this temporary extension retains current requirements in place and does not impose any new obligations or burdens, CDC is committed to working with cruise ship operators who have requested a minimum of 14 days' advance notice to inform their passenger clientele, adjust itineraries as needed, and extend existing contractual arrangements and memorandums of understanding with port, housing, and medical providers.

This Order shall remain in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency; (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations; or (3) January 15, 2022 at 12:01 a.m. (EST).

**Authority**

The authority for these orders is Sections 361 and 365 of the Public Health Service Act (42 U.S.C. 264, 268) and 42 CFR 70.2, 71.31(b), 71.32(b).

Dated: October 25, 2021.

**Sherri Berger,**

*Chief of Staff, Centers for Disease Control and Prevention.*

[FR Doc. 2021-23573 Filed 10-26-21; 11:15 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos. FDA-2010-N-0190; FDA-2012-N-0197; FDA-2014-N-1414; and FDA-2014-N-0913]

**Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrahi, Office of Operations, Food