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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew

**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 framework for a phased resumption of cruise ship passenger operations. CDC also announces requirements for the initial phases of this framework regarding testing of crew members for COVID-19, an integral part of the initial phases prior to resuming passenger operations. This Order applies to cruise ship operators with cruise ships operating in U.S. waters and cruise ship operators who are operating cruise ships outside of U.S. waters, but intend for their cruise ships to return to operating in U.S. waters while this Order remains in effect.

**DATES:** This action is effective October 30, 2020.

**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 establishes a framework for a phased approach to resuming cruise ship passenger operations in U.S. waters. This phased approach will include: (1) Establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2) simulated voyages designed to test a cruise ship operators' ability to mitigate COVID-19 onboard cruise ships; (3) a certification process; and (4) a return to passenger voyages in a manner that mitigates the risk of COVID-19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities.

As part of the initial crew testing phases, this Order additionally contains requirements for: (1) Shoreside COVID-19 laboratory screening testing of all crew currently onboard cruise ships; (2) onboard diagnostic testing capabilities for symptomatic travelers (crew and future passengers); (3) shoreside COVID-19 laboratory screening testing of all newly embarking crew; and (4) continued compliance with complete, accurate, and acknowledged, No Sail Order Response Plans.

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): Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew

##### Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), announces this framework for a phased resumption of cruise ship passenger operations. Considering the continued spread of COVID-19 worldwide and increased risk of COVID-19 on cruise ships, a careful approach is needed to safely resume cruise ship passenger operations. CDC is establishing requirements to mitigate the COVID-19 risk to passengers and crew, prevent the further spread of COVID-19 from cruise ships into U.S. communities, and protect public health and safety. After expiration of CDC's No Sail Order (NSO) on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters.

The initial phases will consist of testing and additional safeguards for crew members. CDC will ensure cruise ship operators have adequate health and safety protections for crew members while these cruise ship operators build the laboratory capacity needed to test future passengers. Subsequent phases will include simulated voyages to test cruise ship operators' ability to mitigate COVID-19 risk, certification for ships that meet specific requirements, and a phased return to cruise ship passenger voyages in a manner that mitigates COVID-19 risk among passengers, crew members, and U.S. communities. These

phases are subject to change based on public health considerations and cruise ship operators' demonstrated ability to mitigate COVID-19 risk. CDC will issue additional orders as needed that will be published in the **Federal Register** and technical instructions that will be subsequently posted on CDC's website.

This Order additionally announces requirements for the initial phases relating to crew testing. CDC considers adequate crew safeguards as demonstrated through laboratory testing for SARS coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, an integral part of the initial phases prior to resuming passenger operations.

##### Previous Orders and Incorporation by Reference

The findings and other evidence relied upon in issuing the No Sail Order and Other Measures Related to Operations signed by the CDC Director on March 14, 2020,<sup>1</sup> as further modified and extended effective April 15, 2020,<sup>2</sup> July 16, 2020,<sup>3</sup> and September 30, 2020<sup>4</sup>—are incorporated herein by reference.

##### 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;

<sup>1</sup> No Sail Order and Suspension of Further Embarkation. <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>. Last accessed October 19, 2020.

<sup>2</sup> No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other>. Last accessed October 19, 2020.

<sup>3</sup> No Sail Order and Suspension of Further Embarkation, Second Modification and Extension of No Sail Order and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail>. Last accessed October 19, 2020.

<sup>4</sup> No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations. <https://www.federalregister.gov/documents/2020/10/05/2020-22030/no-sail-order-and-suspension-of-further-embarkation-third-modification-and-extension-of-no-sail>. Last accessed October 19, 2020.

- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions.

#### Acronyms, Initialisms, and Definitions

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

*aCLI* means additional COVID-like illness signs and symptoms as defined by the Council of State and Territorial Epidemiologists (CSTE) and that are not included in the definitions of ARI, ILI, or pneumonia, or as defined by CDC in technical instructions. CDC will use the most current CSTE definition in effect, which may be found at: <https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/>.

*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-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.

*USCG* means United States Coast Guard, Department of Homeland Security.

(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-like Illness* means ARI, ILI, pneumonia, aCLI, 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, passenger-carrying vessel operating in U.S. waters with the capacity to carry 250 or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.<sup>5</sup>

*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 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 part 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

that were issued between March 14 and September 30, 2020. CDC continues to define cruise ships in this manner 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.

passengers to embark or disembark a cruise ship.

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

*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* means 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 mock voyage or series of mock voyages 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.

*Social distancing* means maintaining a distance of at least 6 feet between one individual and another individual, not gathering in groups, and avoiding crowded places and mass gatherings.

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

#### Background and Need To Establish a Framework for Mitigating the Risk of COVID-19 Onboard Cruise Ships Prior to Resuming Passenger Operations

The coronavirus disease 2019 (COVID-19) pandemic continues to spread rapidly around the world with no U.S. Food and Drug Administration (FDA) authorized vaccine. As of October 30, 2020, a cumulative total of over 44 million cases and nearly 1.2 million confirmed deaths have now been reported worldwide. Even in countries that have managed to slow the rate of transmission, the risks for COVID-19 resurgence remains. In the United States, as of October 29, 2020, there have been over 8.8 million cases and over 227,000 confirmed deaths. Based on the evidence gathered and explained in the No Sail Order issued on March 14, as modified and extended on April 15, July 16, and September 30, 2020, there is ample reason to believe that absent mitigation measures of the type needed to prevent further transmission, cruise ship travel has the potential to exacerbate and amplify the spread of SARS coronavirus 2 (SARS-CoV-2) the virus that causes COVID-19.

<sup>5</sup> Cruise ships are defined in the same manner as in CDC's No Sail Orders, as extended and modified,

Unrestricted cruise ship travel would likely exacerbate and amplify the spread of SARS coronavirus 2 (SARS-CoV-2) the virus that causes COVID-19. On January 20, 2020, the *Diamond Princess* cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID-19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew on board the ship. Among the 3,711 *Diamond Princess* passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID-19, 37 required intensive care, and nine died. Following this outbreak, two voyages of the *Grand Princess* cruise ship were ultimately associated with 159 confirmed COVID-19 cases, including eight deaths.<sup>6</sup>

Because of these events, and the increased risk of transmission on cruise ships, on March 14, 2020, the CDC Director issued a *No Sail Order and Other Measures Related to Operations* directing cruise ships not voluntarily suspending operations to comply with certain measures (85 FR 16628). This followed a March 13, 2020, announcement by Cruise Line International Association (CLIA), the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID-19.<sup>7</sup> Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with new COVID-19 outbreaks. Between March 14 and April 15, 2020, COVID-19 outbreaks were reported on several additional cruise ships with passengers (85 FR 21004).

Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director issued *No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations*, modifying and extending the previous

March 14, 2020 Order, which became effective on April 15, 2020 (85 FR 21004). Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique<sup>8</sup> to continue to engage in cruise ship operations in any international, interstate, or intrastate waterways subject to the jurisdiction of the United States, cruise ship operations were limited, and cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board to ensure a safe work environment and disembarkation for crew members. A cruise ship operator's No Sail Order response plan had to minimize to the greatest extent possible any impact on U.S. Government operations or the operations of any State or local government, or the U.S. healthcare system. While working with cruise ship operators to ensure the completeness and accuracy of these response plans, CDC allowed crew members to disembark from cruise ships in U.S. waters and return home if cruise ship operators formally attested, in writing, to complying with requirements to disembark crew members in such a manner as to minimize the risk to other travelers and communities.

Following the April 15, 2020 Extension, CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS-CoV-2 infections and exposures among crew members.<sup>9</sup> During this period, CDC also further assisted cruise ship operators with humanitarian medical evacuations for people in need of lifesaving support. Under the April 15, 2020 Extension, CDC established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships through a requirement for weekly submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (OMB Control Number 0920-0134, exp. 03/31/2022)". Since then, the EDC form has been used to conduct surveillance for COVID-19 among crew who remained on board cruise ships based on cumulative reports of acute respiratory illness

(ARI),<sup>10</sup> influenza-like illness (ILI),<sup>11</sup> pneumonia, and other clinical indicators of COVID-19 (85 FR 62732).

As of October 30, 2020, EDC reports have shown a total of 6,725 polymerase chain reaction (PCR) tests performed, 296 (4%) of which were positive; 24 hospitalizations; 2 instances of mechanical ventilation; and 15 medical evacuations for crew on ships within U.S. jurisdiction since April 15, 2020. CDC also recommended that ships' surveillance include routine testing for SARS-CoV-2 infection, including intermittent testing of a random sample of symptomatic and asymptomatic crew members.

In addition to reviewing the No Sail Order response plans, CDC continued to update its *Interim Guidance* as new information became available; provided technical expertise to ships with ongoing outbreaks; created cruise ship-specific websites to inform crew members, the public, and partners; and reviewed hundreds of written attestations submitted by cruise operators for safe disembarkation and transfer of crew members.

CDC established a "COVID-19 Color Coding System" for ships applicable to cruise ship operators with an appropriate No Sail Order response plan for crew management. Classification of ships under this system requires cruise company officials to sign an acknowledgment of the completeness and accuracy of their No Sail Order response plans upon completion of CDC review of the plan. CDC assesses the status of a ship by reviewing surveillance data from the weekly EDC form as well as recent embarkations or crew transfers. Additional details regarding the color-coding system and color coding status for individual ships (which is updated weekly) may be found at <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>.

To continue to protect public health and safety, and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director signed a *Second Modification and Extension of No Sail Order and Other Measures Related to Operations* on July 16, 2020, (85 FR 44085), and *Third Modification and Extension of No Sail Order and Other Measures Related to Operations* on September 30, 2020, (85 FR 62732).

<sup>6</sup>Moriarty LF, Plucinski MM, Marston BJ, et al. Public Health Responses to COVID-19 Outbreaks on Cruise Ships—Worldwide, February–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:347–352. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>. Last accessed June 25, 2020.

<sup>7</sup>CDC Travel Health Notice, *COVID-19 and Cruise Ship Travel*, at: <https://wwwncc.cdc.gov/travel/notices/warning/coronavirus-cruise-ship> (originally posted, March 17, 2020). Last accessed June 25, 2020.

<sup>8</sup>Under 42 CFR 71.1, controlled free pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.

<sup>9</sup>CDC, *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew* at: <https://www.cdc.gov/quarantine/cruise/management/interim-guidance-no-sail-order.html>

<sup>10</sup>Acute Respiratory Illness (ARI) is defined as the presence of cough, sore throat, or rhinorrhea in the absence of fever.

<sup>11</sup>Influenza-like Illness (ILI) is defined as fever (100.4 °F [38 °C]) plus either cough or sore throat.

This last order, among other things, continued to suspend passenger operations on board cruise ships through October 31, 2020.

Current scientific evidence suggests that, absent mitigation measures of the type needed to prevent further transmission, cruise ships would continue to pose a greater risk of COVID-19 transmission than other settings. A recent article published in the *Journal of Travel Medicine* by Rocklöv et al. demonstrated that the *Diamond Princess* cruise ship experienced an onboard  $R_0$  (basic reproduction rate) for COVID-19 of 14.8 before ship-wide quarantine was enacted.<sup>12</sup> This means that each case onboard the *Diamond Princess* transmitted COVID-19 to approximately 15 other people. This reproduction rate is approximately four times higher than the  $R_0$  of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID-19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people. In late February/early March, 149 cases of PCR-confirmed COVID-19 (of 589 tour participants) were found among U.S. residents linked to Egyptian Nile Cruises. This heightened rate of transmission onboard cruise ships has also been documented in other academic publications.<sup>13</sup> Absent appropriate interventions to mitigate the spread of COVID-19, cruise ship conditions would likely amplify the spread of an already highly transmissible disease.

Rocklöv et al. surmised that this heightened rate of transmission is due to the high population density on board ships, which are typically more densely populated than cities or most other living situations. While this is one contributing factor, CDC's surveillance data collected through the EDC form and acquired during the period of the No Sail Order show that drastically decreasing population on board, absent other interventions, is not enough to extinguish transmission. Other factors likely contributing to onboard transmission are crews' living and working in close quarters, in a partially enclosed environment, and where social distancing may prove challenging even

with a limited number of people onboard.

In addition, the recent investigation by Payne et al. of transmission onboard a U.S. Navy ship demonstrated high transmission rates and high rates of mild disease and asymptomatic infection among crew.<sup>8</sup> These mild presentations and asymptomatic cases make case detection and isolation and quarantine practices based on clinical presentation alone challenging. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next. This again stresses the need for appropriate interventions, including routine laboratory testing of crew, prior to restarting passenger operations.

Several cruise ship operators have taken steps to improve their public health response to COVID-19. For example, under the co-chairmanship of former Health and Human Services Secretary, Michael O. Leavitt, and former FDA Commissioner, Dr. Scott Gottlieb, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a "Healthy Sail Panel" of subject-matter experts from a variety of disciplines. The World Travel & Tourism Council (WTTC) and Carnival Corporation also recently hosted a global science summit on COVID-19 designed, "to inform practical, adaptable and science-based solutions for mitigating and living with COVID-19." MSC Cruises further established its own industry-led panel with "competency to review policy initiatives, technical innovations, or operational measures related to COVID-19."

To gather more information regarding industry-led efforts to respond to COVID-19 and solicit public input, on July 20, 2020, CDC published a Request for Information (RFI) in the **Federal Register** related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). The document had a 60-day comment period that ended on September 21, 2020 and nearly 13,000 comments were received.

Respondents to the RFI included members of the public, the cruise industry, seaport authorities, and the travel and hospitality industries. A majority of respondents (approximately 75%) expressed support for the resumption of passenger cruising in the U.S. Most of these commenters, however, expressed the need for increased public health measures, including health screening, testing, mask use, social distancing, travel insurance, refunds, and shipboard public health capacity as important

steps to take before cruising resumes. Approximately 25% of respondents, including many previous cruise passengers, were in favor of delaying the resumption of passenger cruising because of the current state of the pandemic, and supported waiting until a vaccine is widely available.

Comments received related to the reduction of number of passengers, the need for routine testing of passengers and crew, social distancing, coordination between CDC and the cruise industry, limiting ports of call to private islands, agreements with local public health and medical facilities, and the economic benefits of cruising. Approximately 98% of respondents supported cruise ship operators denying boarding to passengers with COVID-like illness or confirmed COVID-19 infection, while approximately 65% of respondents supported denying boarding to passengers with known COVID-19 exposure in the previous 14 days before embarkation. A majority of respondents (74%) also supported requiring that cruise ship operators test passengers and crew prior to embarkation. Furthermore, approximately 90% of respondents supported cruise ship operators reducing passenger and crew loads to reduce the risk of COVID-19 transmission, while approximately 85% supported the wearing of face masks by passengers. While CDC bases its public health determinations on the best available science and not on public opinion, the willingness of the public to accept measures to mitigate the risk of transmitting COVID-19 onboard cruise ships is noteworthy. Accordingly, CDC carefully considered these comments in drafting this framework.

CDC also considered alternatives to this framework. One alternative considered was allowing cruise ship operators to return to unrestricted passenger operations without any public health oversight. This alternative was deemed unacceptable because cruise ship travel is known to contribute to COVID-19 transmission. Furthermore, mild presentations and asymptomatic cases make case detection and isolation and quarantine practices challenging absent robust testing. Thus, covert spread of infection among crew may keep the virus circulating from one voyage to the next and passengers infected on cruise ships could further spread COVID-19 into U.S. communities by traveling interstate after cruising. This would have the effect of increasing morbidity and mortality, and burdening federal, state, and local medical and public health infrastructure. This again stresses the

<sup>12</sup> 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. doi: 10.1093/jtm/taaa030.

<sup>13</sup> 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>.

need for appropriate public health oversight.

Public health oversight is further needed to correct a market failure stemming from information asymmetry, *i.e.*, the public is often not fully informed in such a way to adequately determine the extent to which any given measure mitigates their personal risk, particularly in light of asymptomatic cases. CDC is therefore overcoming this market failure by ensuring that the measures taken by cruise ship operators are those that are most likely to adequately mitigate such risks.

Another alternative considered was continuing to issue No Sail Orders as occurred between March 14 and September 30, 2020. However, this alternative was not found to be as optimal as the current framework. The benefits of this framework outweigh the costs of not allowing cruise ships to sail because it allows for flexibility where cruise ships have taken the necessary precautions to mitigate risk, while continuing to prohibit passenger operations onboard ships that have failed to implement such precautions. As such, the current framework represents a tailored approach that was determined to be preferable to the status quo No Sail Order. This framework allows for individual cruise lines to progress through phases at variable paces. This enables cruise lines successfully implementing public health measures to return to passenger operations more quickly while others by necessity may move more slowly. The framework not only encourages cruise lines that are more successful at mitigating the spread of COVID-19 but provides a realistic timeline that anticipates COVID-19 continuing to be present and affecting cruise ship travel.

While the actions taken by some cruise ship operators to improve their public health response to COVID-19 are encouraging, ongoing public health oversight is needed to ensure uniform standards for mitigating the communicable disease risk to crew and prospective passengers. The public health measures in this framework reflect CDC's considered views as to the minimum standards that must be in place prior to resuming passenger operations in a way that will mitigate the risk of COVID-19.

CDC intends to take a phased approach to resuming passenger operations. These phases include: (1) Establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2) simulated voyages designed to test a cruise ship operators' ability to mitigate COVID-19 on cruise ships; (3) a certification process; and (4) a return

to passenger voyages in a manner that mitigates the risk of COVID-19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities. These phases will be further determined based on public health considerations including the trajectory of COVID-19 transmission and the demonstrated ability of cruise ship operators to successfully employ measures that mitigate the risk of COVID-19.

As part of the initial crew testing phases, this Order additionally contains requirements for: (1) Shoreside COVID-19 laboratory screening testing of all crew currently onboard; (2) onboard diagnostic testing capabilities for symptomatic travelers (crew and future passengers); (3) shoreside COVID-19 laboratory screening testing of all newly embarking crew; and (4) continued compliance by cruise ship operators with their complete, accurate, and acknowledged, No Sail Order Response Plans.

#### *Findings and Immediate Action*

The continued spread of the COVID-19 pandemic worldwide, risk of resurgence in countries that have suppressed transmission, and ongoing concerns related to the restart of cruising, supports the establishment of a framework designed to mitigate the risk of COVID-19 onboard cruise ships.

Accordingly, and consistent with 42 CFR 70.2, 71.31(b), and 71.32(b), the Director of CDC ("Director") continues to find that absent measures of the type needed to mitigate further transmission, cruise ship travel exacerbates the global spread of COVID-19, that the scope of this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities. As described in the March 14, 2020, Order, as further modified and extended on April 15, 2020, July 16, 2020, and September 30, 2020, cruise ship travel markedly increases the risk and impact of the COVID-19 disease epidemic within the United States. If unrestricted cruise ship passenger operations were permitted to resume, infected and exposed persons disembarking cruise ships would place federal partners (*e.g.*, Customs and Border Protection and the U.S. Coast Guard), healthcare workers, port personnel, and communities at substantial unnecessary risk. Unrestricted cruise ship travel would also divert and overburden scarce federal, state, and local, public health

and healthcare resources during a pandemic.

The Director also 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>14</sup> This reasonable belief is based on information from epidemiologic and other data included in this document and the information described in the March 14, 2020, Order and the April 15, July 16, and September 30, 2020, modifications and extensions. As a result, absent measures of the type needed to mitigate further transmission, persons on board or seeking to board cruise ships may likely be or would likely become infected with or exposed to COVID-19 by virtue of being on board at a time when cases of COVID-19 continue to be reported in increasingly significant numbers globally.<sup>15</sup> Additionally, persons infected on cruise ships would be likely to transmit COVID-19 to U.S. communities by traveling interstate after cruising.

Accordingly, under 42 CFR 70.2, the Director determines that measures taken by State and local health authorities regarding COVID-19 onboard cruise ships are inadequate to prevent the further interstate spread of the disease. Cruise ships by their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority. Furthermore, local transmission of COVID-19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel. Therefore, federal intervention is needed to require public health measures to prevent the further introduction, transmission, or spread of COVID-19 via cruise ships globally and into U.S. communities.

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). CDC published a Request for Information (RFI) in the **Federal Register** that solicited and

<sup>14</sup> COVID-19 is a communicable disease for which quarantine is authorized under Section 361 of the Public Health Service Act (42 U.S.C. 264) and 42 CFR 70.1, 71.1, as listed in Executive Order 13295, as amended by Executive Orders 13375 and 13674.

<sup>15</sup> Since the March 14, 2020, Order, the number of global cases of COVID-19 reported by the World Health Organization (WHO) has risen from 142,534 to more than 44 million as of October 30, 2020, with nearly 1.2 million deaths. See Situation Reports, WHO, <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>.

obtained public comment related to cruise ship planning and infrastructure, resumption of passenger operations, and additional summary questions (85 FR 44083). In the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because CDC has already obtained public comment and good cause exists to dispense with prior public notice and the opportunity to further comment on this Order.<sup>16</sup> Considering the public health emergency caused by COVID-19 based on, among other things, its potential for spread on board cruise ships, 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. 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, but there would not be a delay in its effective date as the agency has invoked the good cause provision of the APA.

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.

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.

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.

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 described above for the period described below, it is *ordered*:

#### *Framework for Conditional Sailing*

##### *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 cruise ship in U.S. waters and to any person operating a 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.

(4) Cruise ship operators may use the services of professionally licensed and accredited third-party auditors to assist them in meeting the requirements of this framework. Notwithstanding, the cruise ship operator's responsible officials maintain an overall duty and responsibility for meeting the requirements of this framework, including the requirements of any technical instructions or orders. Third-party auditors are prohibited from interfering with CDC's ability to inspect and conduct oversight under this framework, including but not limited to interfering with CDC's ability to interview cruise ship crew and personnel or visually inspect and oversee collection of laboratory specimens and laboratory testing.

Requirements for Protection of Crew for Cruise Ship Operators Operating or Intending To Operate Cruise Ships in U.S. Waters

(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.

(1) The cruise ship operator must have received a determination by CDC that a plan submitted in response to the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (*i.e.*, "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.

(2) 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 March 14 through October 31, 2020, or who voluntarily withdrew their ships during this time period, 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 28 days preceding those ships' expected arrival in U.S. waters and continue to submit the EDC form after the ships' entering U.S. waters.

(3) The cruise ship operator has observed and will continue to observe all elements of its No Sail Order response plan including by following the most current CDC recommendations and guidance for any public health actions related to COVID-19, or if any deviations from the plan have occurred such deviations have been reported and corrective actions taken to the satisfaction of CDC.

(4) The cruise ship operator has arranged for and submitted and will continue to arrange for and submit such laboratory 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 remains in effect. Laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders. CDC may conduct oversight of specimen

<sup>16</sup> See 5 U.S.C. 553(b)(B), (d)(3).

collection, testing, and laboratory procedures, as necessary.

(5) If the cruise ship received any ship-to-ship transfers in the last 28 days, crew were only transferred from a cruise ship with no confirmed COVID-19 or COVID-like illness during the 28 days before the transfer occurred.

(6) If the cruise ship received any land-based embarking crew, such crew were laboratory tested for COVID-19 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.

(7) Following submission of an application for a COVID-19 Conditional Sailing Certificate, the cruise ship operator shall continue to follow these requirements for protection of crew pending approval of the operator's application.

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

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

(a) 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.

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

(c) 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.

#### Agreement With Port and Local Health Authorities

(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.

(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 to determine the number of cruise ships at any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak.

#### 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 or series of simulated voyages 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:

(1) The cruise ship operators shall inform volunteer passengers in writing that they are participating in a simulation of unproven and untested health and safety protocols for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity.

(2) All volunteer passengers must be at least eighteen 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 and not as a condition of employment or in exchange for consideration or future reward. The cruise ship operator must document the informed consent of all participants in writing.

(4) The cruise ship operator must embark additional crew members

beyond safe minimum manning levels only as determined through CDC technical instructions or orders.

(5) 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.

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

(7) 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.

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

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

(10) 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.

(11) 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.

(12) 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 COVID-19 is detected during the simulation.

(13) 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.

(14) 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 request that the cruise ship operator modify its practices or procedures and/or engage in additional simulated voyages 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 shall 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.<sup>17</sup>

(c) A cruise ship operator shall not apply for approval to conduct a simulated voyage until all of CDC's requirements relating to the protection of crew onboard ships 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 under 18 U.S.C. 1001 that all of CDC's requirements relating to the protection 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.

#### Applying for a COVID-19 Conditional Sailing Certificate

(a) A cruise ship operator must submit the following to CDC prior to commencing restricted passenger operations:<sup>18</sup>

(1) A completed CDC registration/application form that must include 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 and of any third-party auditors.

(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 copy of the USCG Certificate of Inspection issued in accordance with 46 CFR 2.01-5 that was in effect for the six months preceding the application.

(5) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting that the cruise ship operator has complied and remains in compliance with CDC's crew protection requirements of prior to applying for a COVID-19 Conditional Sailing Certificate.

(6) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting 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 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.

(7) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting 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.

(8) A certification statement signed under 18 U.S.C. 1001 by the responsible officials attesting 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 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

<sup>17</sup> This written notice should be submitted at least 30 calendar days prior to the date on which the cruise ship operator proposes to conduct the simulation.

<sup>18</sup> These materials should be submitted at least 60 calendar days prior to the date on which the cruise ship operator proposes to commence restricted passenger operations.

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, CDC may require a cruise ship operator to submit proof of having been inspected by any other agency or entity with authority, jurisdiction, or oversight over any aspect of a cruise ship operator's operations.

(e) 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 USCG 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.

(f) 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 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 in marketing materials, on its website, and in offerings for voyages, notify prospective passengers prior to accepting a reservation of any CDC travel advisory, warning, or recommendation relating to cruise travel. Such notification must further advise prospective passengers that, if a threshold of COVID-19 is detected on board the cruise ship during a voyage, the voyage will be ended immediately and the ship returned to the U.S. port of embarkation, and their subsequent travel, including their return home, may be restricted or delayed.

(2) The cruise ship operator must not sail or offer to sail on an itinerary longer than 7 days. CDC may shorten or lengthen the number of days permitted to sail based on public health considerations and as set forth in technical instructions or orders.

(3) 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.

(4) 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.

(5) 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.

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

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

(8) The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing.

(b) In light of public health considerations and based on evidence gained through review and evaluation of cruise operators' practices and procedures, including through simulated voyages, CDC may require the following:

(1) A monitored observation period of passengers prior to embarking.

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

(3) 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 a threshold of 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 end the restricted passenger voyage, cancel future restricted passenger voyages until directed by CDC that such voyages may resume, and return the ship to the U.S. port of embarkation.

(3) 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.

(4) 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.

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

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

(7) Inform ship pilots, ground transportation, air charter 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).

(b) CDC may issue additional technical instructions or orders regarding what measures cruise ship operators must take in the event that COVID-19 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, third-party auditors, 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, third-party auditors, or other persons under the cruise ship operator's employ.

#### Initial Phase COVID-19 Testing Requirements for Protection of Crew

CDC will take a phased approach to resuming passenger operations onboard cruise ships and considers adequate crew safeguards an integral part of its initial phases. Accordingly, it is further ordered:

##### Shoreside COVID-19 Laboratory Screening Testing of All Crew

(1) Within 60 days of the effective date of this Order,<sup>19</sup> cruise ship operators must collect clinical specimens from all crew currently onboard their cruise ships and have those specimens immediately transported and tested by a shoreside laboratory facility. This testing must be conducted by a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory using reverse transcriptase polymerase chain reaction (RT-PCR) tests that are approved, cleared, or authorized for emergency use by the U.S. Food and Drug Administration (FDA).

(2) To help ensure the validity of sampling, testing, and test results, cruise ship operators must contact CDC at [eocevent349@cdc.gov](mailto:eocevent349@cdc.gov) at least 7 calendar days prior to collecting specimens and conducting testing. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory and the cruise

<sup>19</sup> For cruise ship operators with ships that have not been in U.S. waters during the period of the No Sail Order or voluntarily withdrew their ships, the 60-day period will begin upon: (1) CDC confirming to the cruise ship operator in writing that the operator has a complete and accurate NSO response plan, including having submitted to CDC a signed *Acknowledgment of No Sail Order Response Plan Completeness and Accuracy*; and (2) submission of the EDC form for the 28 days preceding the cruise ship's expected arrival in U.S. waters.

ship operator's procurement of specimen collection kits. Include "Laboratory Screening Testing of All Crew Onboard SHIP NAME" in the subject line as part of your request for CDC approval.

(3) CDC's response to the cruise ship operator's email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting crew specimens. CDC may also oversee the onboard collection of crew specimens through remote means allowing for visual observation.

(4) Cruise ship operators must report all laboratory results in aggregate to CDC through the Enhanced Data Collection (EDC) form.

#### Onboard COVID-19 Diagnostic Testing Capabilities for Symptomatic Travelers (Crew and Future Passengers)

(1) During this 60-day period, cruise ship operators in coordination with CDC must develop onboard testing capabilities to test all symptomatic travelers (crew and future passengers) for COVID-19 and close contacts. After this 60-day period, laboratory testing for every crew member must be conducted on a weekly basis or at such other intervals as required by CDC in technical instructions or orders.

(2) All cruise ships must procure rapid RT-PCR point-of-care equipment to test symptomatic travelers. This instrument must be CLIA-waived and have been evaluated on the FDA reference panel for SARS-CoV-2 and demonstrated a lower limit of detection correlating to higher sensitivity. Cruise ship operators must contact CDC prior to procuring this equipment. Antigen testing is not recommended at this time because it is more likely to miss cases of SARS-CoV-2 infection (*i.e.*, lower sensitivity) when compared to RT-PCR testing.

(3) Cruise ship medical clinic staff must be competent in specimen collection, be able to properly use testing equipment, follow all manufacturer's instructions, and have access to and use recommended personal protective equipment (PPE) for specimen collection and handling. CDC may ensure competency by conducting oversight of these practices through remote means allowing for visual observation. In addition, cruise ship operators must maintain onboard SARS-CoV-2 testing equipment to manufacturer's specifications.

(4) Once testing equipment has been obtained and cruise ship medical clinic staff are properly trained in its use, all symptomatic crew onboard the cruise ship must be tested for SARS-CoV-2

infection immediately upon notifying medical staff of symptom onset. These results must be reported to CDC in aggregate through the EDC form.

Shoreside COVID-19 Laboratory Screening Testing of All Embarking Crew

(1) On the day of crew members' embarkation, cruise ship operators must collect specimens for SARS-CoV-2 testing from all embarking land-based crew. Cruise ship operators must immediately transport the specimens to a CLIA-certified laboratory for testing.

(2) This laboratory must use an RT-PCR test that has been approved, cleared, or authorized for emergency use by FDA. Cruise ship operators must report results in aggregate to CDC through the EDC form. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory.

(3) All embarking land-based crew must be immediately quarantined onboard for 14 days. Those who test positive must be isolated until criteria are met for discontinuation of isolation according to the most current CDC guidance. CDC may also oversee the collection of specimens, or the quarantine or isolation of embarking crew, through remote means allowing for visual observation.

Continued Compliance With No Sail Order (NSO) Response Plans

(1) Cruise ship operators must continue to follow their cruise lines' complete, accurate, and acknowledged NSO response plans per the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (*i.e.*, "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)).

(2) Cruise ship operators must also continue to follow CDC's Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew and COVID-19 Color-coding System for Cruise Ships, which may be modified or updated as needed. CDC will notify cruise ship operators of any updates. Ship-to-ship crew transfers and embarkations may continue to impact ships' color-coding status. For additional information about other public health preventive measures, such as social distancing, mask use, and cabin occupancy, refer to CDC's Interim Guidance.

#### *Effective Date and Signature*

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

**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 30, 2020.

**Nina B. Witkofsky,**

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

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**BILLING CODE 4163-18-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

**[30Day-21-20PA]**

#### **Agency Forms Undergoing Paperwork Reduction Act Review**

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "DOP Cross-Site Program Implementation Evaluation of Overdose Data to Action Program" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on 06/15/2020 to obtain comments from the public and affected agencies. CDC did not receive public comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### **Proposed Project**

DOP Cross-Site Program Implementation Evaluation of Overdose Data to Action Program—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

#### **Background and Brief Description**

The Overdose Data to Action (OD2A) program is a comprehensive, national overdose prevention program developed by CDC. The purpose of the OD2A program is to support funded jurisdictions in obtaining high quality, complete, and timely data on opioid prescribing and overdoses, and to use those data to inform prevention and response efforts. OD2A funds a total of 66 recipients (state and local health departments) to implement surveillance and prevention strategies, through a three-year cooperative agreement.

This information collection review is focused on the tools needed to evaluate the unique OD2A program. This information collection includes key informant interviews (KII) and focus groups (FG). The information collection is unique and will be the first evaluation of the OD2A program. There are no other efforts that CDC knows of to obtain program information required to