UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, Plaintiff v. XAVIER BECERRA, Secretary of the Dep't of Health and Human Services, *et al.*, Defendant.	Case No. 8:21-cv-839-SDM-AAS

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION

INTRODUCTION

The State of Florida, having failed to challenge the Order at issue here for six months, and related orders for another six months before that, now asks this Court—on an emergency basis and without the benefit of full briefing on an administrative record—to invalidate the Centers for Disease Control and Prevention's ("CDC") Conditional Sailing Order, and to authorize the unconditional resumption of cruise ship operations, without enforceable restrictions to prevent the spread of COVID-19. The Court should decline the invitation.

Despite recent gains, the United States remains in the midst of a once-in-a-century pandemic that has killed over half a million Americans and three million people worldwide. Early in the pandemic, several deadly outbreaks were clustered on

cruise ships, like the *Diamond Princess* in Japan, and the *Grand Princess* in the San Francisco Bay. These outbreaks required vast expenditures of government resources to evacuate, quarantine, isolate, house, and treat passengers. These experiences demonstrated that cruise ships are uniquely suited to spread COVID-19, likely due to their close quarters for passengers and crew for prolonged periods, and other factors. As a result of these outbreaks, on March 13, 2020, the cruise ship industry's principal trade group, the Cruise Line International Association ("CLIA"), voluntarily suspended passenger operations, and repeatedly extended that voluntary suspension. Not all cruise operators, however, are members of CLIA, and accordingly, many countries, including the United States, paused operations of these high-risk ships while their operators completed plans to ensure a safe environment for travel.

In the United States, the "No Sail Orders" of last year have been superseded by a framework for re-opening known as the "Conditional Sailing Order," or "CSO," which sets reasonable conditions for the operation of cruise ships based on the best available scientific evidence. The CSO provides for a phased re-opening whereby ship operators (1) test crew and develop on-board testing capacity for future crew and passengers, (2) conduct simulated voyages, and then (3) apply for and obtain Conditional Sailing Certificates. Now that CLIA is willing to resume safe sailing, this framework is necessary to ensure the safe re-opening of cruise operations in the United States, and it is based on CDC's plain authority to regulate ships in U.S. waters to prevent the spread of disease.

CDC is working in partnership with the cruise lines—which have not joined Plaintiff's challenge—to expeditiously move through the CSO framework. Currently, the industry is in Phase 2(a), in which cruise ship operators build additional testing capacity and negotiate agreements with port and local health authorities in each jurisdiction in which they intend to dock to ensure that these local authorities agree that any outbreaks can be safely managed. And today, the CDC issued new guidance for cruise ship operators to test their COVID-19 protocols in U.S. waters through simulated voyages and submit an application for a Conditional Sailing Certificate to resume passenger operations.

Plaintiff's proposed injunction would not maintain the status quo so that the Court has time to rule on the underlying issues—it would upend it. The Court should reject this demand for multiple independent reasons. First, Plaintiff lacks standing to bring suit in the first place. The CSO regulates cruise lines, not states. And Plaintiff cannot save its claim to standing by asserting the alleged injuries of its residents as *parens patriae*, or by relying on indirect declines in general tax revenues.

Second, Plaintiff sat on its supposed rights for well over a year while cruise ship operations were restricted. It cannot now establish that irreparable harm would be prevented by letting cruise ships resume operations slightly more quickly than CDC believes is necessary to protect the public's health.

Third, Plaintiff cannot establish a likelihood of success on the merits of their claims. To start, even if the State of Florida were within the zone of interests of the relevant statute—and it is not—the CDC has acted lawfully and reasonably in setting

conditions on the operation of cruise ships, pursuant to clear authority to regulate vessels intending to operate in U.S. ports. The administrative record will show that the agency considered relevant factors, engaged in reasoned decision-making, and came to reasonable conclusions, especially given the extraordinary deference due to Defendants during the ongoing public health emergency. Moreover, in order to bring an "unreasonable delay" claim like the one here, Plaintiff must identify a specific, mandatory agency action that has been delayed; it cannot do so, and the CDC acted reasonably because, under current guidance, cruise ship operators may conduct simulated voyages and commence restricted passenger voyages by mid-summer. Next, Defendants are not required to conduct notice-and-comment rulemaking to condition a license or enter an order under existing regulations during the pendency of a global public health emergency; and Defendants in any event have demonstrated good cause because they did in fact solicit, receive and consider public comments. Finally, Plaintiff has failed to state a claim under the "nondelegation" doctrine because Congress has provided the CDC with manageable standards to apply.

Finally, the balance of equities tips sharply in Defendants' favor, as the threat of further COVID-19 outbreaks on board cruise lines decisively outweighs any economic injury to Plaintiff. For any or all of these reasons, the Court should deny the motion for a preliminary injunction.

BACKGROUND

Statutory and Regulatory Authority. The federal government has a long history of acting to combat the spread of communicable disease, including the

regulation of vessels in interstate and international travel. Congress enacted the first federal quarantine law in 1796 in response to a yellow fever outbreak, authorizing the President to direct federal officials to help states enforce quarantine laws. Act of May 27, 1796, 4 Cong. Ch. 31, 1 Stat. 474 (1796) (repealed 1799); *see Smith v. Turner*, 48 U.S. 283, 300 (1849). Following a subsequent yellow fever outbreak, Congress replaced this Act with a federal inspection system for maritime quarantines. Act of Feb. 25, 1799, 5 Cong. Ch. 12, 1 Stat. 619 (1799). And in 1893, Congress authorized the Secretary of the Treasury to adopt additional regulations to prevent the introduction of disease into the United States or across state lines where the Secretary considered state or local regulation inadequate. Act of Feb. 15, 1893, 52 Cong. Ch. 114, 27 Stat. 449 (1893).

Section 361 of the Public Health Service Act ("PHSA") consolidates and codifies the federal government's "basic authority to make regulations to prevent the spread of [communicable] disease into this country or between the States[.]" H.R. Rep. No. 78-1364, at 24 (1944). The statute authorizes Defendants "to make and enforce such regulations as in [the Secretary's] judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." 42 U.S.C. § 264(a).[1]

[1] Although the statute assigns this authority to the Surgeon General, Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General to the Secretary of Health, Education, and Welfare, now the Secretary of Health and Human Services, 31 Fed. Reg. 8855, 80 Stat. 1610 (June 25, 1966), *see also* An Act to Establish a Dep't of Educ., Pub. L. No. 96-88,

The CDC Director implements this authority through regulations at 42 C.F.R. parts 70 and 71. *See* Control of Communicable Diseases, 82 Fed. Reg. 6890, 6892 (Jan. 17, 2017). Under these regulations, vessels (including cruise ships) are extensively regulated to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one U.S. State or territory into another. For example, "[w]henever the Director has reason to believe that any arriving carrier . . . is or may be infected . . . with a communicable disease, he/she may require detention, disinfection, . . . or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 C.F.R. § 71.32(b). The CDC "may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease." *Id.* § 71.31(b). It also "may issue a controlled free pratique [i.e., permission for a carrier to enter a U.S. port, disembark, and begin operations under certain stipulated conditions] to the carrier stipulating what measures are to be met." *Id.*; *see also id.* § 71.1(b). Moreover, the regulations provide that whenever the CDC Director determines that the measures taken by State authorities "are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or

§ 509, 93 Stat. 695 (October 17, 1979) (codified at 20 U.S.C. 3508(b)). Although the Office of the Surgeon General was later re-established, the Secretary retains these authorities.

possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary[.]" *Id*. § 70.2.

The No Sail Order and Extensions. Pursuant to these authorities, on March 14, 2020, the CDC issued an order entitled "*No Sail Order and Suspension of Further Embarkation.*" *See* 85 Fed. Reg. 16628-03 (Mar. 24, 2020) ("NSO"). The NSO contains extensive findings about the spread of COVID-19 on board cruise ships, including information about the deadly outbreaks on board specific ships in the early months of the pandemic, and describes the voluntary suspension of operations by CLIA members. *Id*. at 16630-31.[2] The NSO was intended to provide "the necessary pause in operations to develop and implement an appropriate and robust plan to prevent and mitigate the spread of COVID-19[.]" *Id*. at 16631. The NSO contains several requirements for cruise ships that operate in U.S. waters or intend to arrive in U.S. waters during the effective period of the NSO; most relevant here, the NSO required all disembarkation of passengers to be undertaken in coordination with relevant agencies, and prevented any embarkation or operations except as specifically permitted in consultation with the CDC. *Id*. at 16631.

The CDC extended the NSO three times, and made additional data-based findings in each extension about the continued transmission of COVID-19 on board cruise ships, and the continued need for federal action in light of the inadequacy of

[2] The cruise ship response efforts by the CDC in early 2020 were immense and resource-intensive for the CDC and for all levels of government. *See* Treffiletti Decl. ¶¶ 8-23.

local control.[3] The last extension of the NSO, through Oct. 31, 2020, found that, despite the continuing voluntary suspension of operations, and the cooperation of the industry, "[c]ruise ships continue to be an unsafe environment" and were the location of multiple outbreaks and deaths during the period of voluntary suspension. 85 Fed. Reg. at 62732, 62735-36. This extension described the dangers of premature re-opening, found a need for additional precautions and additional assessment of proposals for re-opening, and imposed additional conditions on the granting of controlled free pratique. *Id*. at 62735-38.

Conditional Sailing Order. On Oct. 30, 2020, the CDC issued the *Framework for Conditional Sailing and Initial Phase COVID–19 Testing Requirements for Protection of Crew*, 85 Fed. Reg. 70153-01 (Nov. 4, 2020). The CSO announced that "[a]fter expiration of CDC's [NSO] on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters." *Id*. The CDC reviewed the NSO extensions and the evidence gathered to date regarding mitigation of risk on board cruise ships, including the results of scientific studies of onboard transmission, progress made by cruise lines, and public comments received in response to a request for information. *Id*. at 70154-57.[4] *See also* Treffiletti Decl. ¶¶ 33-45.

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[3] *See No Sail Order and Suspension of Further Embarkation: Notice of Modification and Extension and Other Measures Related to Operations*, 85 Fed. Reg. 21004 (Apr. 15, 2020); *No Sail Order and Suspension of Further Embarkation; Second Modification and Extension of No Sail Order and Other Measures Related to Operations*, 85 Fed. Reg. 44085-01 (July 21, 2020); *No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations*, 85 Fed. Reg. 62732-01 (Oct. 5, 2020).

[4] *See also* CDC Regulations.gov, *RFI* Cruise Ship Planning, Comments (July 21, 2020), *available at* https://www.regulations.gov/document/CDC-2020-0087-0001/comment (last visited around May 5, 2021) (around 13000 comments received); Treffiletti Decl. Ex. A (selected comments).

Based on this record, the CDC determined that a phased approach to granting controlled free pratique was appropriate:

- Phase 1: Crew testing. Ship operators to conduct shoreside testing of crew, develop on-board testing capacity, begin testing crew weekly, and submit results to the CDC.[5]

- Phase 2: Simulated voyages. These are designed to test ship operators' protocols for mitigating COVID–19 onboard, and require them to "document the approval of all U.S. port and local health authorities where the ship intends to dock or make port," including adequate agreements to deal with housing and medical care in event of an outbreak.

- Phase 3: Certification. After successfully completing simulated voyages, ship operators may apply for a Conditional Sailing Certificate.

- Phase 4: Return to passenger voyages, in a manner that mitigates the risk of COVID-19 spread.

85 Fed. Reg. at 70153, 70158-59; Treffiletti Decl. ¶ 33.

Although Phase 1 was originally planned to last 60 days, ship operators reported that supply issues prevented them from procuring onboard laboratory equipment, and the CDC extended the time for compliance. *See* Treffiletti Decl. ¶¶ 46-49. As of April 26, 2021, 95% of cruise ships covered by the CSO (56 out of 59 ships in U.S. waters) have performed the required mass screening testing of all crew, and 80% (47 of 59 ships) have fully completed Phase 1. *Id.* ¶ 49.

[5] Given the briefing schedule for a preliminary injunction, Defendants have not had time to compile the voluminous administrative record for the CSO (which incorporated the findings of the NSO and extensions). Defendants will produce the administrative record when they move for summary judgment. The Declaration of Captain Aimee Treffiletti is submitted herewith to provide additional background about the process for developing the CSO, information about the current state of re-opening, and an explanation of the likely consequences of the requested injunction.

Meanwhile, on April 2, 2021, the CDC announced the guidance for the next phase. In Phase 2(a), ship operators are preparing to conduct simulated voyages, including by complying with new technical instructions for crew testing and negotiating agreements with port and local health authorities.[6] In developing these requirements, the CDC consulted extensively with state, local, and international health authorities. *See id*. ¶¶ 50-55. On April 28, 2021, following multiple meetings with industry representatives, the CDC sent a letter to cruise ship operators, emphasizing the agency's commitment to the phased resumption of passenger operations around mid-summer, and clarifying several aspects of the Phase 2(a) guidance. *Id*. ¶ 52 & Ex. B. Among other things, that letter explains that the CDC will respond to an application within five business days, clarifies that multiport agreements are acceptable, updates the vaccination and testing requirements, and provides that "[i]n lieu of conducting a simulated voyage," ship operators may attest "that 98 percent of crew are fully vaccinated" and that "95 percent of passengers" will be "verified by the cruise ship operator as fully vaccinated prior to sailing."[7]

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[6] *See* CDC, *Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew*, available at https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html; CDC, *Technical Instructions for a Cruise Ship Operator's Agreement with Port and Local Health Authorities under CDC's Framework for Conditional Sailing Order*, available at https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html.

[7] The Governor of Florida has issued an Executive Order stating that "[b]usinesses in Florida are prohibited from requiring patrons or customers to provide any documentation certifying COVID-19 vaccination." Fl. Exec. Order No. 21-81, § 2 (Apr. 2, 2021); *see also* Orlando Sentinel, *DeSantis' ban of vaccine passports could lead to showdown with businesses in Florida*, https://www.orlandosentinel.com/politics/os-ne-prem-ne-vaccination-passports-florida-20210415-p5ih3mwtjrervlnnufbe3mijgi-story.html. It is unclear whether the Governor's order will delay cruise ships from resuming operations in Florida.

On May 5, 2021, the CDC released guidance regarding simulated voyages, providing specific instructions for how cruise ship operators may test their health and safety protocols in U.S. waters through simulated voyages, including the requirements for simulated voyages, guidance for CDC inspections, and operational procedures for risk mitigation on simulated and restricted voyages. Treffiletti Decl. ¶ 58 & Exs. C, D. While the CDC may adjust these recommendations based on public health considerations and other factors, cruise ship operators now have all the necessary instructions they need to conduct simulated voyages, apply for a COVID-19 conditional sailing certificate, and ultimately begin restricted passenger voyages as they are able to meet the various requirements. *Id*. The CDC anticipates that such voyages could begin by mid-summer. *Id*. ¶ 74.

Cruise lines have advocated for faster re-opening, or lifting of the CSO, but they continue to work with the CDC and have not, to date, challenged the CSO in court. *See* Treffiletti Decl. ¶ 74 (describing ongoing engagement with industry). CLIA is publicly advocating for a "phased resumption" of cruising to begin in early July, which is consistent with current CDC guidance and the April 28 letter.[8]

This Litigation. The State of Florida filed suit, raising five counts against Defendants, and seeking, *inter alia*, a permanent injunction against the CSO in its entirety. Compl., ECF No. 1. The present motion seeks the same injunction as a preliminary matter.

[8] *See* CLIA, Cruise Industry COVID-19 Facts and Resources, https://cruising.org/en/cruise-industry-covid-19-facts-and-resources.

STANDARDS FOR A PRELIMINARY INJUNCTION

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). "In order to obtain [a preliminary injunction], a party must establish four separate requirements—namely, that (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." *Swain v. Junior*, 961 F.3d 1276, 1284–85 (11th Cir. 2020) (citation omitted). "[F]ailure to meet even one dooms" Plaintiff's motion. *Wreal, LLC v. Amazon.com*, 840 F.3d 2144, 1248 (11th Cir. 2016). Plaintiff here has an even higher burden. The "chief function of a preliminary injunction is to preserve the status quo until the merits of the controversy can be fully and fairly adjudicated." *Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville*, 896 F.2d 1283, 1284 (11th Cir. 1990). "Mandatory preliminary relief[,]" which changes the status quo, "is particularly disfavored, and should not be issued unless the facts and law clearly favor the moving party." *Powers v. Sec'y, Fla. Dep't of Corr.*, 691 F. App'x 581, 583 (11th Cir. 2017) (citation omitted).

ARGUMENT

I. PLAINTIFF LACKS STANDING.

Plaintiff lacks standing. The CSO regulates cruise lines, not states. Florida may not invoke the interests of its residents to support standing in a suit against the federal government, and Florida's attempt to invoke the indirect effect of federal policy on its general tax revenues is effectively a generalized grievance. Even if lower general tax revenues were a legally cognizable injury, Florida can only speculate that any harm will in fact occur or that its injury is fairly traceable to the CDC Order, given the effect of the independent decisions of third parties and the course of the virus on Florida's finances.

The CSO does not require Plaintiff to do or refrain from doing anything—it regulates cruise ships, none of whom have challenged it in court. *See Massachusetts v. Mellon*, 262 U.S. 447, 482 (1923) ("Nor does the statute require the states to do or to yield anything."). Because Plaintiff is not "the object of the [challenged] government action[,]" its standing is "substantially more difficult" to establish. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992); *see also Wilderness Soc. v. Griles*, 824 F.2d 4, 10-12 (D.C. Cir. 1987) (addressing threatened injuries in standing law).

To start, Plaintiff is mistaken to suggest that it has standing in its *parens patriae* capacity to invoke the well-being of its residents. *See* Pl.'s Mot. for Prelim. Inj. ("Pl.'s Mot."), ECF No. 9 at 21-22. While a state may in some circumstances be able to sue as *parens patriae* for its citizens, "it is no part of its duty or power to enforce their rights in respect of their relations with the federal government. In that field[,] it is the

United States, and not the state, which represents them as parens patriae." *Mellon*, 262 U.S. at 485-86; *see also Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n. 16 (1982); *Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 179-83 (D.C. Cir. 2019); *Graham v. Schweiker*, 545 F. Supp. 625, 627 (S.D. Fla. 1982).

For its own part, Florida has not demonstrated a legally cognizable Article III injury to itself. To obtain the prospective relief it seeks, Plaintiff bears the burden of showing that it "is immediately in danger of sustaining some direct injury" and that the "threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (citation omitted).

Plaintiff claims that it "is likely to continue to suffer . . . economic harm" as a result of lower general tax revenues. Pl.'s Mot. at 22.[9] But "loss of general tax revenues as an indirect result of federal policy is not a cognizable injury in fact." *El Paso Cty., Texas v. Trump*, 982 F.3d 332, 339 (5th Cir. 2020); *see also see Arias v. DynCorp*, 752 F.3d 1011, 1055 (D.C. Cir. 2014) (same); *Iowa ex rel. Miller v. Block*, 771 F.2d 347, 353 (8th Cir. 1985) (same). The reality is that "'virtually all federal policies' will have 'unavoidable economic repercussions.'" *El Paso*, 982 F.3d at 339 (quoting *Pennsylvania v. Kleppe*, 533 F.2d 668, 672 (D.C. Cir. 1976)). Accordingly, complaints

[9] Plaintiff also gestures at a procedural injury, claiming CDC deprived Florida of the opportunity to comment on the challenged order. Pl.'s Mot. at 21 n.10. Leaving aside the fact that the CDC provided opportunity for comment on the safe resumption of passenger operations, *see* 85 Fed. Reg. at 44083-85; *Spokeo, Inc. v. Robin*, 136 S. Ct. 1540, 1548-49 (2016). Plaintiff "cannot satisfy the demands of Article III by alleging a bare procedural violation." *Spokeo, Inc.*, 136 S. Ct. at 1550; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (rejecting claim that plaintiffs have standing because "they have been denied the ability to file comments" and explaining that "a procedural right *in vacuo*—is insufficient to create Article III standing").

about such losses typically amount to "the sort of generalized grievance about the conduct of government, so distantly related to the wrong for which relief is sought, as not to be cognizable for purposes of standing." *Kleppe*, 533 F.2d at 672.

Even if Plaintiff's alleged economic injury were cognizable, its injury is premised on "continued closure of the cruise industry[,]" Johnston Decl., ECF No. 9-25, ¶ 5, as "the important summer cruising season is fast approaching," Pl.'s Mot. at 22. However, Plaintiff "present[s] no concrete evidence to substantiate [its] fears" that the cruise operations will not imminently resume under the challenged policy, "but instead rest[s] on mere conjecture about possible governmental actions." *See Clapper v. Amnesty Int'l*, 568 U.S. 398, 420 (2013). Contrary to Plaintiff's fears, the CSO—unlike the NSOs—establishes a "framework for a phased resumption of cruise ship passenger operations," 85 Fed. Reg. at 70,153, in order to effectuate "a return to passenger voyages in a manner that mitigates the risk of COVID-19," *id*. at 70157. Indeed, Plaintiff's own "evidence" speculates that guidelines "vital for the cruise lines" to resume operations under the challenged order "[c]ould be just days away," Pl.'s Ex. 7 at 5; *see also* Pl.'s Ex. 28 at 3 ("possibility of a summer restart of service"), consistent with the CSO's goal of resuming safe voyages by mid-summer. And that speculation is confirmed by today's release of guidance for the next phases of the CSO. Treffiletti Decl. ¶ 58. It is therefore likely that many cruises can operate on the schedule currently planned by the industry. Even if Plaintiff had established "an objectively reasonable likelihood that" the cruise industry would continue to be shut down through the summer in the United States under the challenged order, an

"'objectively reasonable likelihood' . . . is inconsistent with [the] requirement that 'threatened injury must be certainly impending to constitute injury in fact.'" *Clapper*, 568 U.S. at 410 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).[10]

Plaintiff also fails to demonstrate causation or redressability. Here, Plaintiff provides nothing but speculation to support its theory that any lost general tax revenues are fairly traceable to the CDC's order, as opposed to the independent decisions of third parties, like cruise lines and passengers. Plaintiff provides evidence of *past* tax revenue purportedly associated with cruise ships from *before the COVID-19 pandemic*. *See* Johnston Decl. ¶ 4; *see also* Pl.'s Ex. 20 at 44; Pl.'s Ex. 21 at 29; Pl.'s Ex. 22 at 10; Pl.'s Ex. 23 at 36; Pl.'s Ex. 24 at 27; Pl.'s Ex. 25 at 3. And Plaintiff's primary declarant merely "*[a]ssum[es]* . . . that the cruise industry would return to 2019 numbers" if the challenged order is vacated. *See* Johnston Decl. ¶ 5 (emphasis added). But a state's impaired tax revenues during an ongoing pandemic "is driven by countless variables, from the performance of the broader economy" to whether or not a resurgence of COVID-19 will occur, as well as independent decisions of cruise ship operators, tourists, airlines, and businesses in the state. *See XY Planning Network LLC v. SEC*, 963 F.3d 244, 253 (2d Cir. 2020); *see also Clapper*, 568 U.S. at 413

[10] In "cases in which the plaintiff alleges that governmental action will be taken directly against him[,] . . . the Court has assessed the likelihood that the clash between the government and the plaintiff will in fact occur." *Griles*, 824 F.2d at 11. A plaintiff may establish a sufficiently imminent injury in that setting "if the threatened injury is 'certainly impending' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Dreihaus*, 573 U.S. 149, 158 (2014) (citation omitted). Plaintiff does not claim a threat of injury emanating directly from government conduct in this case, however. *See* Pl.'s Mot. at 22. Here, the CDC is "act[ing] directly against a third party"—the cruise ship industry—"whose expected response in turn will [purportedly] injure the plaintiff." *Griles*, 824 F.2d at 11.

(refusing to "endorse standing theories that require guesswork as to how independent decision-makers will exercise their judgment"); *Simon v. E. Kentucky Welfare Rights Org.*, 426 U.S. 26, 42-43 (1976). Plaintiff's submissions do not attempt to estimate what revenues would be absent CDC action – i.e., if cruising were legally permitted to resume without federal public health oversight and against CDC advice.

Additionally, Plaintiff's injury is premised on speculation that either (1) no ship-borne outbreak of COVID-19 (including a variant) would occur, or (2) if a ship-borne outbreak did occur, the weighty costs of addressing the emergency would not be placed on the State. *See XY Planning Network*, 963 F.3d at 253 (concluding that State's theory "assumes away the potential downsides of" their preferred approach). Without adequate planning and regulation to mitigate COVID-19 risks, cruise ship operations during the pandemic may result in "State and local public health officials" facing major "burden[s] supporting cruise ships attempting to make port with ill passengers or crew and struggl[ing] to repatriate passengers and crew while also protecting the limited medical assets" available in their community. 85 Fed. Reg. at 44087; *see also* Treffiletti Decl. ¶¶ 37, 51-55.

The CDC has concluded that without adequate precautions, a cruise ship outbreak exacerbating and amplifying the spread of the virus is quite likely given the unique characteristics of cruise ships. *See* Treffiletti Decl. ¶ 75; 85 Fed. Reg. at 44090-91. Plaintiff does not evaluate the impact of such outbreaks on the cruise economy or its overall tax revenue. And Plaintiff makes no effort to address the economic implications of would-be cruise passengers forgoing a cruise in the absence of the

assurances of safety that accompany federal regulation during the ongoing pandemic.[11] All these what-ifs and could-bes highlight Plaintiff's speculation in asserting an imminent injury caused by the challenged actions. Because the supposed injuries, at most, arise from the kind of "unavoidable economic repercussions of virtually all federal policies[,]" they do not support standing. *XY Planning Network*, 963 F.3d at 252 (quoting *Kleppe*, 533 F.2d at 672).

II. FLORIDA HAS NOT DEMONSTRATED IRREPARABLE HARM.

"A delay in seeking a preliminary injunction of even only a few months . . . militates against a finding of irreparable harm." *Wreal, LLC*, 840 F.3d at 1248. "Indeed, the very idea of a *preliminary* injunction is premised on the need for speedy and urgent action to protect a plaintiff's rights before a case can be resolved on its merits." *Id*. Here, Plaintiff seeks to "preliminarily enjoin Defendants from enforcing, or giving any effect to, the [CSO,]" ECF No. 9-30, but offers no explanation why it waited nearly six months after the temporary emergency order was issued to seek judicial review—let alone stay or preliminarily enjoin it. Plaintiff's "unexplained delay undercuts any sense of urgency and, therefore, Plaintiff has failed to demonstrate sufficient need for a preliminary injunction." *Seiko Kabushiki Kaisha v. Swiss Watch Int'l, Inc.*, 188 F. Supp. 2d 1350, 1356 (S.D. Fla. 2002).

Indeed, Plaintiff says that the "extraordinary and drastic remedy" of a preliminary injunction, *see All Care Nursing, Inc. v. Bethesda Mem. Hosp., Inc.*, 887 F.2d

[11] Commenters overwhelmingly supported regulatory policies that would mitigate the risk of COVID-19 transmission. *See* 85 Fed. Reg. at 70,156; Treffiletti Decl. ¶ 38.

1535, 1537 (11th Cir. 1989), is warranted because "the important summer cruising season is fast approaching," Pl.'s Mot. at 22. But if Plaintiff had timely petitioned for judicial review, its "claim [w]ould have been brought at such a time as to allow consideration of the merits" long before the summer "without requiring entry of a" preliminary injunction. *See Hill v. McDonough*, 547 U.S. 573, 584 (2006) (quoting *Nelson v. Campbell*, 541 U.S. 637, 650 (2004)). Accordingly, this Court must "apply 'a strong presumption against the grant of a'" preliminary injunction. *See id*. (quoting *Nelson*, 541 U.S. at 650); *see also Lanvin Inc. v. Colonia, Inc.*, 739 F. Supp. 182, 192-93 (S.D.N.Y. 1990) ("A movant for extraordinary relief cannot mask an ongoing failure on its part to mitigate its damages as an ongoing instance of irreparable harm.").

Plaintiff's attempt to demonstrate irreparable harm falls short for an additional reason: the injury it alleges is insufficient. "Even if denial of injunctive relief would present some monetary injury to the plaintiff[], . . . not finding *irreparable* injury" would be proper. *Snook v. Trust Co. of Georgia Bank of Savannah, N.A.*, 909 F.2d 480, 487 (11th Cir. 1990) (emphasis in original). "Financial damage alone is insufficient to warrant injunctive relief." *Seiko Kabushiki Kaisha*, 188 F. Supp. 2d at 1355. Although a threat to a plaintiff's existence or continued operations may constitute irreparable harm, Florida presents no evidence that its purported cruise ship tax revenue is needed to keep the state in financial operation pending judicial review of the challenged order. *See Alsop v. Desantis*, No. 8:20-cv-1052, 2020 WL 4927592, at *4 (M.D. Fla. Aug. 21, 2020) (Merryday, J.)); *Cal. Ass'n of Private Postsecondary Schs. v. DeVos*, 344 F. Supp. 3d 158, 170-71 (D.D.C. 2018); *see also Odebrecht Const., Inc. v.*

Sec'y, Fla. Dep't of Transp., 715 F.3d 1268, 1288 (11th Cir. 2013) (finding irreparable the "substantial nature of the . . . harm" that constituted approximately "100% of [plaintiff's] revenues"); *cf. VNA of Greater Tift Cty., Inc. v. Heckler*, 711 F.2d 1020, 1034 (11th Cir. 1983) (considering allegation of "being forced out of business").

Here, Florida speculates that lost tax revenue associated with cruise ship operations might be $82 million. Johnston Decl. ¶ 5.[12] But in a state with a Chief Executive that has recommended a Fiscal Year 2021-2022 budget of $96.6 *billion*,[13] the amount at issue is roughly 0.085% of the state's budget. Plaintiff's suggestion that "*any* damages," no matter how slight, "in a suit against a defendant with sovereign immunity are irreparable per se" surely "stretches too far," *Air Transp. Ass'n of Am. Inc. v. Export-Import Bank of the United States*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012), and "is inconsistent with [the] characterization of injunctive relief as an extraordinary remedy[,] *Winter*, 555 U.S. at 22. Moreover, "[t]here are several possible means by which [Florida] could recover" its less-than-hoped-for tax revenues other than a suit against Defendants because the state, like a public utility, has captive taxpayers and any losses are "recoverable [by adjustments] in the [state]'s

[12] The corrected Fitz-Patrick Declaration estimates total revenue losses during the pandemic for some local ports. *See* ECF No. 25-26. Even assuming that Florida could assert these losses on behalf of the ports, which is unlikely, the declaration makes no attempt to connect those losses to CDC action or even to cruise lines.

[13] Governor Ron DeSantis Announces His "Florida Leads" Budget Proposal for FY 2021-2022, https://www.flgov.com/2021/01/28/governor-ron-desantis-announces-his-florida-leads-budget-proposal-for-fy-2021-2022/ (last visited May 5, 2021).

[tax] rates." *Cf. Wisc. Gas Co. v. FERC*, 758 F.2d 669, 675 (D.C. Cir. 1985); *see also Florida v. Mellon*, 273 U.S. 12, 18 (1927).[14]

Given the speculative nature of the "injuries" here, *see* Part I, *supra*, issuing a preliminary injunction here would be inconsistent with the Eleventh Circuit's emphasis that "the asserted irreparable injury must be neither remote nor speculative," *Swain*, 961 F.3d at 1292 (citation omitted), to be awarded only ""upon a clear showing that the plaintiff is entitled to such relief," *Winter*, 555 U.S. at 22.[15]

III. PLAINTIFF CANNOT DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS.

A. Plaintiff Lacks Statutory Standing.

Counts 1-4 raise claims under the APA, and Plaintiff lacks statutory standing to raise such claims. The APA's grant of standing to persons "adversely affected or aggrieved by agency action within the meaning of a relevant statute," 5 U.S.C. § 702, does not extend to the full reach of Article III, and is satisfied only if the plaintiff's interests are "arguably within the zone of interests to be protected or regulated by the

[14] Plaintiff also asserts that it provided $20 million in unemployment benefits to cruise industry employees since March 1, 2020. *See* Heckman Decl., ECF No. 9-19, ¶ 3. But Plaintiff provides only speculation that any of those individuals—let alone a substantial number of them—would leave the unemployment rolls and resume working in the cruise industry if the CSO were enjoined, especially as "[c]ruise ship crew are primarily foreign nationals" meaning ships are not primarily hiring in Florida. Treffiletti Decl. ¶ 69. And as the State reopens, it is just as likely that these individuals will leave unemployment and find work elsewhere. Moreover, Plaintiff fails to account for federal reimbursement of state unemployment spending. *See* American Rescue Plan of 2021, Pub. L. No. 117-2, 135 Stat. 4 (Mar. 11, 2021). Plaintiff has not "shown that the alleged loss is unrecoverable[.]" *Wisc. Gas*, 758 F.2d at 675.

[15] Plaintiff also relies on *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018). *See* Pl.'s Mot. at 22 n.11. But that case only highlights how Plaintiff's evidence of irreparable injury "does not measure up to the kind of detailed . . . analysis about the expected impact of an agency regulation that courts have relied on to find standing[,]" let alone irreparable harm. *Washington v. HHS*, 482 F. Supp. 3d 1104, 1117 (W.D. Wash. 2020) (citing *Azar*, 911 F.3d at 572).

statute" that the plaintiff says was violated. *See Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970); *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129-30 (2014). Thus, even if Florida could establish Article III standing as result of supposed injuries to its tax revenues, that injury is not within the zone of interests of the applicable statute or regulation. It cannot reasonably be assumed that, in "[t]he particular language of" Section 264(a), "Congress intended to protect" a State government's general tax revenue. *See Air Courier Conference of Am. v. Am. Postal Workers Union AFL-CIO*, 498 U.S. 517, 524-25 (1991). The regulations are aimed at public health conditions on board vessels. And while the CSO explicitly takes into account the public health burden on state and local governments, it is not designed to protect, or even consider, state tax revenues. Plaintiff thus cannot establish a likelihood of success on any APA claim.[16]

B. The CSO Does Not Exceed the CDC's Authority.

1. The CSO's restriction of cruise operations pending the implementation of reasonable COVID-19 health and safety protocols falls comfortably within the CDC's authority to prevent the introduction, transmission, and spread of

[16] The Eleventh Circuit has recognized a carve-out for some *ultra vires* actions where the plaintiff is alleging that the agency acted clearly outside its statutory authority. *Chiles v. Thornburgh*, 865 F.2d 1197, 1210-11 (11th Cir. 1989). The question of whether an plaintiff can evade the zone of interests requirement by asserting an equitable *ultra vires* cause of action is pending before the Supreme Court in *Biden v. Sierra Club*, No. 20-138 (cert. granted Oct. 19, 2020). Here, it is not clear that Plaintiff has even raised such a claim. And to the extent this reasoning means that Florida need not establish statutory standing for the Count 1 argument that the CDC was acting outside statutory authority, Florida would still need to demonstrate statutory standing for the argument that the CDC acted outside its *regulatory* authority and must show that Florida is within the zone of interests of the relevant statute to challenge the CDC's application of its own regulations.

communicable disease into and within the United States. The PHSA vests the Secretary with broad authority "to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases" from abroad or among the states. 42 U.S.C. § 264(a). The plain text of the statute thus evinces a legislative determination to defer to the "judgment" of public health authorities about what measures they deem "necessary" to prevent contagion, *see id.*—a determination made in the light of history and experience, given the death toll caused by past epidemics like yellow fever, *see supra* at p.5. And the examples Congress gave of specific measures the Secretary may take to control communicable diseases—which are illustrative, not exhaustive—underscore the breadth of this authority, showing that it may infringe on personal liberties or property rights to protect the public health, including the "detention" of individuals, 42 U.S.C. § 264(b)–(d), and even the "destruction" of property, *id.* § 264(a).

The Secretary has delegated this authority to the public health experts at the CDC, and the agency's regulations reflect the commonsense notion that, to avert the spread of communicable diseases, ships entering U.S. ports may be detained, inspected, and permitted to disembark only under specified circumstances. For example, Section 71.32(b) provides that when "any arriving carrier" "is or may be infected or contaminated with a communicable disease," the CDC Director "may require [its] detention, disinfection, . . . or other related measures . . . as he/she considers necessary to prevent the introduction, transmission, or spread of

communicable disease." 42 C.F.R. § 71.32(b). Likewise, Section 71.31(b) authorizes the CDC to "require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease." *Id.* § 71.31(b). And the CDC "may issue a controlled free pratique to the carrier stipulating what measures are to be met," *id.*, as a condition of receiving "permission to enter a U.S. port, disembark, and begin operation," *id.* § 71.1.

Notably, Plaintiff does not contend that these regulations exceed the CDC's statutory authority—indeed, it concedes that, "[p]roperly read, these regulations make sense as an outflow of § 264," Pl.'s Mot. at 13. The CSO falls squarely within these regulations, and that alone resolves Plaintiff's claim that the order exceeds CDC's authority. In essence, the CSO requires that, "as a condition of obtaining or retaining controlled free pratique," 85 Fed. Reg. at 70158, arriving ships show that they have implemented reasonable COVID-19 preventive measures, have adequate testing capacity and can operate with risk mitigation measures, and will not burden already-strapped federal, state, and local resources if infections arise.

Requiring that ships take such reasonable protective measures as a condition of obtaining controlled free pratique falls well within the agency's authority and is amply supported by the available evidence. The CSO applies to cruise ships that currently operate in (or intend to enter) U.S. waters, *see* 85 Fed. Reg. at 70153, and therefore applies to "arriving carrier[s]" within the meaning of 42 C.F.R. § 71.32(b). It is premised on explicit findings about the risk of transmission of COVID-19 on

cruise ships, explaining that many operators have struggled to follow CDC guidance and prevent outbreaks even without passengers on board, *see* 85 Fed. Reg. at 70156, and thus establishes that the CDC has reason to believe that such carriers "[are] or may be infected or contaminated with a communicable disease," 42 C.F.R. § 71.32(b), or "present a threat of introduction of communicable diseases into the United States," *id.* § 71.31(a).[17] And as a condition of obtaining "controlled free pratique," *id*. § 71.31(b), it requires that ships take now-commonplace "related measures"—like infection precautions, testing, and emergency planning—that the CDC has found are necessary to prevent the spread of COVID-19, *see id*. §§ 71.31(b), 71.32(b); 85 Fed. Reg. at 70158-63.[18]

If there were any gap between the CDC's authority in Part 71 and the CSO—and there is not—it would be amply filled by 42 C.F.R. 70.2. The CSO, like the earlier NSO and its extensions, finds that State and local measures are inadequate to control the threat of the disease on board cruise ships. *See* 85 Fed. Reg. at 16631, 21006, 44091, 62736-37, 70157. For example, the CSO states that "[c]ruise ships by

[17] Plaintiff suggests that any "detention" of a ship under these regulations is necessarily time-limited. Pl.'s Mot. at 12-13. The CSO primarily imposes specific conditions on the granting of controlled free pratique. But even if the CSO were viewed as requiring "detention," it would still be authorized. The regulations do not impose a specific time limit on detention, and the CDC may require "completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease," 42 C.F.R. 71.31(b), and/or "other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases."

[18] Indeed, the regulations themselves contemplate such "[p]ublic health prevention measures," including the "review of travel documents, records review, and other non-invasive means, to determine [an] individual's health status and potential public health risk to others," including "physical examination" and the "collection of human biological samples for laboratory testing as may be needed to diagnose the presence or extent of infection with a quarantinable communicate disease." 42 C.F.R. § 71.1.

their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority," and that "local transmission of COVID–19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel." *Id.* at 70157. Cruise ships are, by purpose and operation, conveyances of international and interstate travel, and single cruise ships have been responsible for outbreaks affecting multiple countries. *See generally* CSO; *see also* Alaska. Br., ECF No. 19-1 at 3 (describing Alaska as a "destination" for ships, not the point of embarkation). The CSO also explains in great detail that the orders are reasonably necessary to prevent the further transmission and spread of the pandemic, and finds that "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." 85 Fed. Reg. at 70157. This evidence-based conclusion is both reasonable and obvious—local authorities cannot adequately control conditions on cruise ships that move between multiple jurisdictions because they cannot inspect and enforce conditions on their operation outside the local jurisdiction in question. Indeed, while Plaintiff criticizes the CDC for allegedly "refus[ing] to consider measures by Florida," Pl.'s Mot. at 12, it never explains what those supposed measures are, much less how they are "[]sufficient" to prevent contagion," 42 C.F.R. § 70.2.

2. Plaintiff's contention that the CSO nevertheless exceeds the CDC's statutory authority—despite falling firmly within its regulations—thus appears to rest

on the notion that the order "shut[s] down the cruise industry" entirely. Pl.'s Mot. at 13. Indeed, Plaintiff goes so far as to call the CDC order a "'ruse' designed to 'keep the industry docked,'" and to question whether the agency is dealing with "the cruise industry in good faith." *Id.* at 7 (citation omitted). In fact, the CDC has for months worked closely with cruise operators—none of which have joined this suit—to move toward the resumption of passenger operations, which it hopes to do by mid-summer. Treffiletti Decl. ¶ 52. In the meantime, nothing in the statute forbids the agency from withholding controlled free pratique to any ship—or many ships, even for an extended period of time—until it is safe for them to resume operations.

As noted above, the plain text of the statute confers broad authority on the Secretary to exercise his "judgment" to take action that he deems "necessary" to avert the international and interstate spread of contagion. 42 U.S.C. § 264(a); *see Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984) (where the text is clear, courts "must give effect to the unambiguously expressed intent of Congress"). Congress's choice of such broad language must be given effect, as "Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion." *City of Arlington, Texas v. FCC*, 569 U.S. 290, 296 (2013); *see Gonzales v. Oregon*, 546 U.S. 243, 258-59 (2006) (characterizing similar language authorizing "necessary" action as granting "an agency broad power to enforce all provisions"). It is commonplace for "legislative options [to] be especially broad" in areas implicating "medical and scientific uncertainties[.]" *Marshall v. United States*, 414 U.S. 417, 427 (1974).

The statutory language exudes flexibility and deference to the judgment of the public health experts at the CDC, and it logically includes regulation of the conveyances of international and interstate travel, including the temporary imposition of conditions for operation during a pandemic. *Cf. Indep. Turtle Farmers of Louisiana, Inc. v. United States*, 703 F. Supp. 2d 604, 619 (W.D. La. 2010) (finding PHSA authorized ban on sale of baby turtles in light of findings about spread of disease). "Congress' intent, as evidenced by the plain language of the delegation provision [of Section 264], is clear: Congress gave the Secretary of HHS broad power to issue regulations necessary to prevent the introduction, transmission or spread of communicable diseases." *Brown v. Azar*, No. 1:20-CV-03702-JPB, 2020 WL 6364310, at *7 (N.D. Ga. Oct. 29, 2020), *appeal docketed*, No. 20-14210 (11th Cir.); *see also Chambless Enters., LLC v. Redfield*, No. 3:20-CV-01455, 2020 WL 7588849, at *5 (W.D. La. Dec. 22, 2020) (similar), *appeal docketed*, No. 21-30037 (5th Cir.); *Louisiana v. Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977) (similar).[19]

That conclusion is buttressed by the findings in the CSO. The CDC determined that its regulations in this area, and the CSO in particular, are necessary to prevent the introduction and spread of COVID-19 in interstate and international

[19] Plaintiff inaccurately characterizes the CSO as a "shutdown" of an entire "industry." *See* Pl.'s Mot. at 3, 14. The NSOs of last year temporarily paused operations in the highest risk portion of an industry (large cruise ships) while operations were already broadly voluntarily suspended during a deadly pandemic, an extraordinary situation. The CSO actually lifts the NSO and sets out a framework for re-opening subject to conditions. Regardless, the pause in operations is doubtless temporary now that there is a path to re-opening, and it is well within CDC's authority to prevent interstate and international spread of communicable diseases caused by ships moving in interstate and international travel.

travel. *See, e.g.*, CSO, 85 Fed. Reg. at 70157 ("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."); *see also id*. (finding "evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease" based on current data). And the agency has long interpreted this statutory authority to include setting conditions on the operation of ships in U.S. ports. *See supra* pp. 5-7.

Plaintiff argues that the broad grant of authority in the first sentence of § 264(a) is implicitly narrowed by that provision's second sentence, which indicates that the agency "may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of [infected or contaminated] animals or articles . . . , and other measures, as in his judgment may be necessary." 42 U.S.C. § 264(a). Plaintiff contends that the enumerated list is effectively exhaustive, but that contention is foreclosed by other subsections of § 264 itself. Those subsections make plain that the broad grant of authority in the first sentence of § 264(a) is not confined to the specific intrusions on private property described in the second sentence. *See, e.g.*, *Independent Turtle Farmers of La., Inc.,* 703 F. Supp. 2d at 619-20 (holding that the second sentence of § 264(a) is illustrative, not exhaustive); *see also Brown*, 2020 WL 6364310, at *8 (similar).[20]

[20] Plaintiff's invocation of various other canons of statutory interpretation, Pl.'s Mot. at 10-11, cannot override the statutory text. The Supreme Court has emphasized that courts should not resort to such rules of thumb when the statute is clear. *See Sebelius v. Cloer*, 569 U.S. 369, 381 (2013).

Even if the first sentence in 264(a) were implicitly narrowed by the second sentence, the CSO is still squarely within the agency's statutory authority. The CSO imposes a set of conditions that is very similar to the types of public health enforcement actions relating to vessels laid out in that language, which include inspection, disinfection, destruction of property, and "other measures." Even on Plaintiff's reading, the statutory list thus contemplates actions with respect to sites, objects, or animals that are, or could be, infected with a disease. The CSO includes just such actions. It requires (for a specific category of high risk ships): on-board testing capacity and regular testing during the duration of the order; agreements with ports as to how to handle potential outbreaks, including housing and medical care; completion of a simulated voyage to demonstrate the adequacy of the ship's hygiene, testing, and outbreak protocols; and an application for a Conditional Sailing Certificate that demonstrates compliance with these requirements. *See supra* pp. 9. Cruise ship operators now have all the information needed to move into operations. *Id.* These requirements may be onerous or time-consuming from the perspective of the cruise lines, but they are not different in kind than the other types of inspection, hygiene, and safety protocols listed in the statute. Indeed, in some respects they are *less* intrusive than the examples Congress set out, as the CSO does not require the "detention" or "destruction" of any property. 42 U.S.C. § 264(a). Plaintiff's

contention that the CSO conditions are too onerous goes only to Plaintiff's second count; it does not negate the CDC's authority to act when warranted.[21]

Amicus argues that the requirement for agreements with port and local health authorities is beyond the agency's statutory authority. But the CDC does not, as Alaska suggests, "indirectly regulate the State." Alaska Br. at 9. Rather, 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 one or more simulated voyages or restricted passenger voyages as a condition of receiving or retaining controlled free pratique, including the approval of the ship's plans for medical care and housing. The purpose of this requirement is to ensure that cruise operators have pre-arranged with port authorities how operations and outbreaks will be handled during the pandemic – e.g., that if a cruise line's outbreak plan is to shunt thousands of potentially infected passengers onto a small community in Alaska that does not have housing or medical facilities, the cruise line must have the local authority's consent

[21] Plaintiff relies heavily on recent cases regarding a different CDC order that prohibits certain evictions. *See, e.g., Tiger Lily, LLC v. HUD*, 992 F.3d 518 (6th Cir. 2021) (declining to stay a judgment against the CDC's eviction moratorium); *Skyworks, Ltd. v. CDC*, No. 5:20-cv-2407, 2021 WL 911720 (N.D. Ohio Mar. 10, 2021) (declaring that the eviction order exceeds CDC's statutory authority). Other courts have disagreed and held that the eviction order is authorized, *see, e.g.*, *Brown*, 2020 WL 6364310, at *7; *Chambless Enters.,* 2020 WL 7588849, at *5, and the Government respectfully submits that the cases cited by Plaintiff are wrongly decided. Moreover, the eviction cases are inapposite because the courts in those cases were evaluating a readily distinguishable order; they in no way considered CDC's statutory authority to regulate vessels. For example, in declining to enter a stay, the Sixth Circuit motions panel—whose decision is not "strictly binding" even within that Circuit, *Wallace v. FedEx Corp.*, 764 F.3d 571, 583 (6th Cir. 2014)—based its decision in part on its conclusion that "[r]egulation of the landlord-tenant relationship is historically the province of the states." *Tiger Lily*, 992 F.3d at 523. The same is decidedly not true of health conditions on board large ships in interstate and international travel that dock at U.S. ports; this area is clearly subject to federal regulation and oversight pursuant to the authority described in detail above.

to do so and must have made arrangements for adequate housing and care. Nothing in the CSO or technical instructions requires states or local authorities to agree to such plans; nor does the CSO impose any penalties on state and local authorities. Treffiletti Decl. ¶ 53. Nothing about that requirement is an unreasonable condition on a grant of controlled free pratique, nor in excess of the CDC's authority. And to the extent the Court finds the statute ambiguous, the CDC's reasonable interpretation of it merits deference. *See Chevron,* 467 U.S. at 843-44 (agency's interpretation of ambiguous language given "controlling weight" unless "arbitrary, capricious, or manifestly contrary to the statute").[22]

C. The CSO Is Not Arbitrary and Capricious.

Plaintiff's contention that the CDC Order was arbitrary and capricious is equally meritless. Under this standard, courts do not ask whether an agency's "decision is the best one possible or even whether it is better than the alternatives," *FERC v. Electric Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016); instead, courts "ensure that the [agency] engaged in reasoned decisionmaking[,]" *id.* at 784. This review is uniquely deferential in the context of public health judgments made in the midst of a deadly global pandemic. As Chief Justice Roberts observed, when public health officials "'undertake[ ] to act in areas fraught with medical and scientific

[22] Plaintiff's passing suggestion that the CSO addresses a "major question" that Congress could not have intended to delegate to the CDC, Pl.'s Br. at 2, 10 & nn.4-5, does not withstand scrutiny. If agencies were generally denied the authority to take actions with, for example, an economic effect of $100 million or more, as Plaintiff argues, *id*. at 10 & n.4 (citing 5 U.S.C. § 804(2)), then the Congressional Review Act—which contemplates that agencies will indeed issue such rules, and gives Congress an opportunity to disapprove of them—would make little sense.

uncertainties,' their latitude 'must be especially broad.'" *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief). "Where those broad limits are not exceeded, they should not be subject to second-guessing by an 'unelected federal judiciary,' which lacks the background, competence, and expertise to assess public health and is not accountable to the people." *Id.* (quoting *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 545 (1985)).

As set forth above, the CSO findings are based on extensive experience, specific data, and consideration of public and industry input. *See supra* pp. 7-9. Plaintiff's assertions of error are meritless. First, Plaintiff argues that that Defendants "ignored important aspects of the problem" by failing to "consider the fact that a vaccine would be available long before the Order expires in November 2021" and by making "inadequate efforts to consider the significant developments on that front since." Pl.'s Mot. at 14-15; *see also* Alaska Br. at 10 (high vaccination rates). But "[i]t is a foundational principal of administrative law that a reviewing court must review only the information that was before the agency at the time of its decision in assessing whether that decision was permissible." *Salmeron-Salmeron v. Spivey*, 926 F.3d 1283, 1286 (11th Cir. 2019). The Court cannot invalidate the CSO on these grounds because, at the time of the CSO, no vaccines had been authorized, *see* 85 Fed. Reg. at 70154, and the CDC was not in a position to consider their availability and efficacy. Even if the Court could consider such an argument, it is incorrect. The CDC has considered the availability of vaccines in devising and issuing its technical

instructions and guidance to implement the CSO—documents that Plaintiff conspicuously does not challenge here. *See, e.g.*, Pl.'s Ex. 14 at 3 (vaccinating crew); Pl.'s Ex. 13 (local agreements include vaccination component); Treffiletti Decl. ¶ 67 & Ex. B (letter permitting certain highly vaccinated cruises without simulated voyages). The Treffiletti Declaration further examines the data and explains why the availability of vaccines does not justify lifting of the CSO. Treffiletti Decl. ¶¶ 59-72.

Second, Plaintiff argues that the "lock down" of the cruise industry is not rationally connected to the facts presented, citing other CDC guidance that recognizes that Americans may travel abroad to board cruise ships, and claiming that the CDC fails to consider measures taken by state and local governments and the cruise industry. Pl.'s Mot. at 15-16. To the extent Plaintiff is pointing to experiences post-dating the CSO, they cannot be considered in evaluating the reasonableness of the CSO. Moreover, while the CDC does not currently prohibit individual Americans from going on foreign cruises, it does strongly advise against it, and recommends testing of all returning passengers and quarantine depending on the circumstances. *See* Treffiletti Decl. ¶ 77.[23] "While CDC does not have data indicating what percentage of airline travelers may choose to go overseas to engage in cruise travel, contrary to CDC's recommendations, experience and common sense suggests that this number is significantly less than those passengers who would choose to cruise from a port in the United States if cruise ship operations were to immediately

[23] *See also* CDC, Covid-19 and Cruise Ship Travel, Level 4 Travel Notice, https://wwwnc.cdc.gov/travel/notices/covid-4/coronavirus-cruise-ship.

resume." *Id.*[24] Nor should the lack of prohibition on foreign cruises be taken as an indication that foreign cruises are perfectly safe. *Id.* ¶¶ 41, 78-81 (explaining that some foreign cruises have led to significant COVID-19 outbreaks, that others are in a location of low COVID-19 prevalence and operating under conditions similar to the CSO, and that still others are not collecting the necessary data).[25] That the CDC has not attempted in this instance to restrict the personal travel of individual Americans abroad hardly renders its regulation of cruise ships in U.S. waters arbitrary.

Plaintiff's additional argument that CDC failed to consider measures taken by state and local governments or the cruise industry is incorrect. As noted above, the CDC reasonably found that state and local governments cannot adequately regulate a ship whose operations are international and interstate in nature. *See supra* pp. 25-26. Moreover, the CDC explicitly considered the measures proposed by the cruise ship industry and the voluntary measures taken to date. *See* 85 Fed. Reg. at 70156 (describing Healthy Sail Panel ("HSP") and other industry proposals); Treffiletti Decl. ¶¶ 43-45 (describing participation in the HSP). And the CDC has continued

[24] Amicus adds that the testing requirement for using PCR is uniquely arbitrary because an air traveler returning to America from a cruise abroad would only be required to do an antigen test. Alaska Br. at 10-11. The cruise environment represents a uniquely high-risk setting, and use of the more reliable test was prudent during Phases 1 and 2, but based on the data gathered to date, the CDC is updating the guidance to permit antigen testing during later phases. *See* Treffiletti Decl. ¶¶ 56-57. It was moreover not practicable to require the heightened test only for air travelers returning from cruises abroad because the CDC does not currently track who went on a cruise abroad. *Id.* ¶ 77.

[25] Other countries are being more cautious. Canada, for example, has banned cruise ships into 2022. *See, e.g.,* Transport Canada, Government of Canada announces one-year ban for pleasure craft and cruise vessels (Feb. 4, 2021), https://www.canada.ca/en/transport-canada/news/2021/02/government-of-canada-announces-one-year-ban-for-pleasure-craft-and-cruise-vessels.html.

engaging with the industry. *See* Treffiletti Decl. ¶ 74. The CDC in fact partially adopted recommendations of the HSP, including the use of a phased approach and the requirement for emergency plans. *Id*. ¶ 45. The CDC's conclusion is further underscored by the difficulty that cruise lines had implementing safety measures and controlling COVID-19 among crew during the period of suspension, and by outbreaks on foreign voyages. 85 Fed. Reg. at 70155-56; Treffiletti Decl. ¶ 41.[26] In any event, Florida does not identify or describe the supposedly adequate measures it has imposed on cruise ships that would mitigate the risk of COVID-19.

Third, Plaintiff claims that Defendants "ignored lesser alternatives" such as "imposing safety protocols." Pl.'s Mot. at 16. This is a puzzling contention in light of the fact that the entire purpose of the CSO is to impose health and safety protocols. It sets up a series of protocols as pre-conditions that the cruise lines must meet before resuming operations. *See supra* p. 9. The CSO made explicit findings about the need to implement testing before the next phases. *See* 85 Fed. Reg. at 70156; *see also* Treffiletti Decl. ¶ 56 (explaining specifically the need for PCR testing during early phases). The simulated voyages will allow an opportunity to practice and test the COVID-19 mitigation protocols. *See* 85 Fed. Reg. at 70157; *see also* Treffiletti Decl. ¶ 58. And the certification process reports back the safety measures implemented and

[26] The CDC's long experience in dealing with health issues on board cruise ships buttresses this finding as well. The CDC's Vessel Sanitation Program oversees safety protocols for preventing the spread of diseases causing gastroenteritis on board cruise ships, and "even in regard to a well-understood, documented, and researched public health phenomenon on cruise ships, for which the cruise ship industry receives extensive instruction, training, and monitoring, breakdowns in cruise ship operators' health and safety protocols can be expected to occur." Treffiletti Decl ¶¶ 6-7.

the results of the simulated sailing. *See* 85 Fed. Reg. at 70159; *see also* Treffiletti Decl. ¶ 58. Plaintiff's assertion that the CDC did not consider other alternatives seems to be an assertion that the CDC did not choose its apparently preferred alternative—to re-open and hope that the cruise lines will adopt adequate health and safety measures on their own. Re-opening with only voluntary health and safety measures that are unproven and untested in U.S. waters during a pandemic is more likely to risk spreading COVID-19 than a supervised approach and was explicitly considered and rejected by the CDC. *See* 85 Fed. Reg at 70157 (stressing need for oversight); Treffiletti Decl. ¶¶ 40-44.

Fourth, Plaintiff claims that Defendants failed to explain supposedly differential treatment of the cruise industry versus other industries. Pl.'s Mot. at 16-17. Plaintiff may disagree with the CDC's conclusion, but the CDC considered the facts—which show that cruise ships are unique. The CSO found markedly higher transmission rates on board cruise ships than exist in other settings; crew and passengers live onboard for prolonged periods of time in enclosed spaces in which social distancing is challenging at best. *See* 85 Fed. Reg. at 70156 (also citing multiple scientific studies). The Treffiletti Declaration provides additional support, explaining that contract tracing required for cruise passengers in early 2020 was far greater than that for air passengers during the same time frame, and that cruise ships have unique conditions on board that exacerbate transmission. Treffiletti Decl. ¶¶ 21-22, 76. Plaintiff asserts that a cruise ship is like an airplane or a hotel, but offers nothing in

support of that opinion. The data contradicts Plaintiff's unfounded claim, and the agency has engaged in reasoned decisionmaking.

Fifth, Plaintiff complains that the CDC has not provided cruise lines "an opportunity to complete the [CSO] framework," supposedly contradicting its own decision that phased re-opening is appropriate. This is inaccurate, as demonstrated by the April 28 letter and the recently published guidance on simulated voyages. *See supra* pp. 10-11; *see also* Treffiletti Decl. ¶¶ 57-58. It is also not an argument that any particular action the CDC has taken is arbitrary. At most, it is an argument that the CDC unlawfully delayed some unspecified agency action that would permit faster re-opening, which fails for the reasons discussed below. *See* Part III.D, *infra*.

D. There Is No Unreasonable Delay.

Plaintiff has no likelihood of success on its claim that the CDC "unreasonably delayed" action to "allow the cruise industry to safely re-open." Pl.'s Mot. at 17. Section 706(1) permits judicial review of agency inaction, but only within strict limits. Courts can only compel "*discrete* agency action that it is *required to take*." *Norton v. Southern Utah Wilderness Alliance,* 542 U.S. 55, 64 (2004) ("*SUWA*") (emphasis in original); *Yusim v. Dept' of Lab.*, 645 F. App'x 967, 968 (11th Cir. 2016). This standard reflects the common-law writ of mandamus, which the APA "carried forward" in Section 706(1). *SUWA*, 542 U.S. at 63. Thus, Section 706(1) grants judicial review of withheld or delayed agency action only if a federal agency has a "ministerial or non-discretionary" duty amounting to "a specific, unequivocal

command." *Id*. at 63-64. "The limitation to *required* agency action rules out judicial direction of even discrete agency action that is not demanded by law . . . ." *Id*. at 65. Here, Plaintiff has not, and cannot, identify any "specific, unequivocal command" in the statute for the CDC to take any particular action on any particular timeframe; rather, the statute confers broad discretion on the agency to act when necessary. While CDC is committed to a re-opening process, there is no "nondiscretionary duty" requiring that to happen immediately despite an ongoing threat of contagion.

Even if Plaintiff had identified some specific, unequivocal command that could suffice for mandamus, its unreasonable delay claim would fail. *See generally Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 79-80 (D.C. Cir. 1984) ("*TRAC*") (identifying 6 factors to consider). There is nothing unreasonable about the agency not immediately re-opening the cruise lines for unrestricted business. Congress has not imposed a timeline by which the CDC must act, nor provided any standard by which the Court could evaluate the timeframe for agency action. The CDC has explained that full implementation of the CSO has been hindered by delayed compliance in Phase 1, the need to evaluate data and draft the guidance, and consultations with partners, all while getting new agency leadership up to speed in early 2021. Treffiletti Decl. ¶ 50. In light of "the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency," *Mashpee Wampanoag Tribal Council, Inc. v. Norton*, 336 F.3d 1094, 1102 (D.C. Cir. 2003), the agency has acted reasonably. In any event, with the most recent guidance, the cruise lines now have a path to re-opening, and the claim is moot.

E. Notice-and-Comment Procedures Were Not Required

Plaintiff claims that the CDC failed to provide notice and comment, Pl.'s Mot. at 17-20, but those procedures were not required here for at least three reasons.

First, the challenged agency action is an order, not a rule. *See* 85 Fed. Reg. at 70,157 (explaining that the "Order is not a rule within the meaning of the [APA], but rather an emergency action taken under the existing authority of [several rules]"). Specifically, the action is a declaratory order conditioning free pratique, which is a license. The APA defines an "order" as "the whole or a part of a final disposition, [including a disposition] declaratory in form, of an agency in a matter other than rule making but including licensing[.]" 5 U.S.C. § 551(6). It defines "licensing," in turn, to "include[] agency process respecting . . . conditioning of a license[.]" *Id.* § 551(9). And a "'license' includes the whole or part of an agency permit, certificate, approval . . . or other form of permission[.]" *Id.* § 551(8). The CSO sets forth certain "condition[s] of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters." 85 Fed. Reg. at 70,158. "Controlled Free Pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions." 42 C.F.R. § 71.1. Accordingly, free pratique is a license, and the CSO is an order imposing conditions on free pratique, not a rule.

Second, even if the order were a rule, the APA provides that notice-and-comment rulemaking is not required "when the agency for good cause" determines notice-and comment is "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This exception is "an important safety valve to be

used where delay would do real harm." *See United States v. Dean*, 604 F.3d 1275, 1278-79 (11th Cir. 2010) (citation omitted); *see also Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004); *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 n.15 (5th Cir. 1979) (citing *Reeves v. Simon*, 507 F.2d 455, 458-59 (Temp. Emer. Ct. App. 1974)). The agency's finding here, which must be reviewed "on the basis of the information available to the agency when it made the decision," *see Vt. Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 547 (1978),[27] more than meets that standard; cruise ships could not be allowed to resume normal operations on October 30, 2020, without posing an unreasonable danger to the public. The CSO lasts for a limited period of time[28] and is based, in part, on extensive interaction with the cruise industry and States such as Plaintiff. In this evolving situation, the public health emergency amply justifies the order taking immediate effect without opportunity for notice and comment. *See Reeves*, 507 F.2d at 459 (finding good cause exemption properly invoked to respond to "a temporary, but highly disruptive, national emergency").

Third, "[e]ven assuming that the APA require[d CDC] to" undergo notice and comment to issue the CSO, "there was no 'prejudicial error'" to Florida here. *See Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385

[27] Even if Plaintiff's suggestion that "the good-cause exemption . . . no longer applies in April 2021" were correct, *see* Pl.'s Mot. at 19, which it is not, the "reviewing court must review only the information that was before the agency at the time of its decision in assessing whether that decision was permissible," *Salmeron-Salmeron*, 926 F.3d at 1286. Plaintiff inappropriately asks the Court to engage in a "sort of Monday morning quarterbacking." *See Vt. Yankee*, 435 U.S. at 547.

[28] The CSO "remain[s] in effect until the earliest of (1) the expiration of the Secretary of [HHS's] declaration that COVID-19 constitutes a public health emergency; or (2) the CDC Director rescinds or modifies the order based on specific public health or other consideration; or (3) November 1, 2021." 85 Fed. Reg. at 70,163.

(2020) (quoting 5 U.S.C. § 706). Notice and comment "allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons." *Dean*, 604 F.3d at 1278 (quoting *Miami-Date Cty. v. EPA*, 529 F.3d 1049, 1059 (11th Cir. 2008)). The CDC solicited and considered comments on a detailed request for information that serves the same purpose. *See supra* p. 8. Moreover, the challenged order sets forth a broad framework for the resumption of cruise ship operations in a manner that mitigates the spread of COVID-19 and explicitly contemplates implementation "though additional orders" and "additional technical instructions." 85 Fed. Reg. at 70,158. The CDC has worked closely with Florida, among other stakeholders, to consider and incorporate its views, even when issuing technical guidance for the phased resumption of cruise ship operations in the months after the CSO was issued. *See* Treffiletti Decl. ¶¶ 37, 54-55. While conveying its concerns during that time period, Florida "certainly had . . . notice" of the CSO. *See Little Sisters*, 140 S. Ct. at 2385. Under these circumstances, Florida "do[es] not come close to demonstrating that [it] experienced any harm" from lack of pre-promulgation notice of the CSO, "let alone that they have satisfied the harmless error rule"— in this suit six months after issuance. *See Little Sisters*, 140 S. Ct. at 2385; Treffiletti Decl. ¶¶ 54-55. Indeed, Florida notes that "[a]n agency must consider and respond to significant comments received during the period for public comment," Pl.'s Mot. at 19, but it does not identify the comments it made to the CDC over the past several months, and it does not explain how the CDC allegedly failed to address

those comments in this unique emergency context. *Cf. Air Transp. Ass'n of Am. v. Civil Aeronautics Bd.*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984).

F. The Statute is Constitutional.

Plaintiff has not demonstrated a likelihood of success on its nondelegation claim. Although Plaintiff argues that Section 264 is an unconstitutional delegation of legislative power, Pl.'s Mot. at 20, "Congress does not violate the Constitution merely because it legislates in broad terms," *Touby v. United States*, 500 U.S. 160, 165 (1991), and the Supreme Court has not invalidated a statute on nondelegation grounds since 1935, *see Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019). The CDC's authority to promulgate public health regulations necessary to prevent the spread of disease should not be the first. As another district court recently explained, 42 U.S.C. § 264's limitation of agency action to measures that are "necessary" "to prevent the introduction, transmission, or spread of communicable diseases" into the United States or among the states, provides a sufficient intelligible principle, and is analogous to other statutes which had been upheld. *See Chambless*, 2020 WL 7588849, at *10-11. Congress has clearly authorized at least direct public health regulation of transport vessels in interstate and international commerce. Plaintiff's nondelegation challenge here easily fails.

IV. THE BALANCE OF HARMS FAVORS THE CDC.

As established above, Florida cannot establish an imminent threat of irreparable harm that this Court can redress. Faced with the purely speculative effect of an injunction on the behavior of third parties, the Court must balance the

judgment of public health authorities that the CSO is necessary to contain the spread of COVID-19. *See* 85 Fed. Reg. at 70157 (finding that unrestricted cruising "would place federal partners . . . , healthcare workers, port personnel, and communities at substantial unnecessary risk" and "divert and overburden scarce federal, state, and local, public health and healthcare resources during a pandemic."). The Treffiletti Declaration establishes that, in her "professional judgment, based on nearly 20 years of professional experience and the science gathered regarding SARS-CoV-2 transmission, . . . absent the protections afforded by the CSO's phased approach, allowing cruise ship operators to immediately return to unrestricted passenger travel (i.e., travel subject only to voluntary measures to address the threat of COVID-19) would likely exacerbate and amplify the spread" of the disease. Treffiletti Decl. ¶ 75.

In response, Florida does not present any contrary evidence from any public health authority that supports re-opening under current circumstances. Plaintiff argues only that "the health of the local economy" is part of the analysis. Pl.'s Mot. at 24. Perhaps, but the balance of harms here does not weigh in favor of vacatur. After all, a precipitous re-opening that causes a resurgence of cases or additional outbreaks would harm both the public and Florida's economy. In a matter last year evaluating Florida's own COVID-19 policies, this Court found that "the threatened harms to the public outweigh decisively the injury — if any — to the plaintiffs." *Alsop*, 2020 WL 4927592, at *4–5 (and collecting cases). The same is true here.

V. PLAINTIFF'S REQUESTED RELIEF IS OVERBROAD.

Even assuming Plaintiff has established standing to press any claims, it certainly has not established standing to seek relief *outside of Florida*. As the Supreme Court has confirmed, any remedy ordered by a federal court must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established"; a court's "constitutionally prescribed role is to vindicate the individual rights of people appearing before it"; and "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1931-34 (2018). "[W]hen a court goes further than that, ordering the government to take (or not take) some action with respect to those who are strangers to the suit, it is hard to see how the court could be acting in the judicial role of resolving cases and controversies." *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring). Plaintiff has not shown why relief outside Florida is needed to remedy its injuries.

If Florida somehow has standing to seek nationwide relief, issuing a preliminary injunction that is larger in scope than required to provide Florida complete relief would be an abuse of discretion. *See New York v. DHS*, 969 F.3d 42, 88 (2d Cir. 2020); *Azar*, 911 F.3d at 584; *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2428-29 (2018) (Thomas, J., concurring).

CONCLUSION

The Court should deny Plaintiff's motion for a preliminary injunction.

Dated: May 5, 2021

Respectfully submitted,

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, Plaintiff v. XAVIER BECERRA, Secretary of the Dep't of Health and Human Services, *et al.*, Defendant.	Case No. 8:21-cv-839-SDM-AAS

DECLARATION OF CAPTAIN AIMEE TREFILETTI
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

I, Aimee Treffiletti, declare as follows:

1) I am the Program Chief of the Centers for Disease Control and Prevention's (CDC) Vessel Sanitation Program (VSP). VSP is part of the Water, Food, and Environmental Health Services Branch (WFEHSB) in the National Center for Environmental Health's (NCEH) Division of Environmental Health Science and Practice at CDC. CDC is an agency within the U.S. Department of Health and Human Services (HHS). I hold the rank of Captain in the U.S. Public Health Service. The U.S. Public Health Service is one of the uniformed services of the United States.

Members of its Commissioned Corps hold service ranks equivalent to officers of the Navy and Coast Guard, along with corresponding in-service medical titles.

2) I received a Bachelor of Science in Geoscience from William Smith College and a Master in Public Health (MPH), *Environmental Health – Industrial Hygiene Concentration,* from the University of California, Berkeley, School of Public Health. I am also certified as a Registered Environmental Health Specialist (REHS) by the National Environmental Health Association. The REHS is a professional credential through the National Environmental Health Association, an association of environmental health professionals. The REHS credential signifies competency in a range of environmental health issues, including clean air, safe food and potable water, emergency response, vector control, sewage sanitation, occupational health, and hazardous material handling.

3) Prior to assuming my current position, I served in the VSP as Assistant Deputy Program Chief and an Environmental Health Officer. Between 2008 and early 2020, I conducted almost 700 cruise ship public health inspections and trained over 4,000 cruise ship managers and supervisors on maritime public health principles. I also worked as an Industrial Hygienist in CDC's Office of Health and Safety and as an Environmental Health Scientist in the Agency for Toxic Substances and Disease Registry within HHS.

4) VSP is an applied environmental health program with a clearly defined mission to help the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illness on cruise ships in U.S. waters. The program's

environmental health officers review, inspect, and provide feedback on cruise ship sanitation, food safety, water safety, ventilation, and vector control activities during routine biannual ship inspections.

5) I have served as the Program Chief of the VSP since 2016. My duties include developing and maintaining partnerships with other Federal agencies and international agencies, including the U.S. Coast Guard, CDC's Division of Global Migration and Quarantine, the U.S. Food and Drug Administration, U.S. Customs and Border Protection, the National Sanitation Foundation, the World Health Organization, the European Union Ship Sanitation Program, the Public Health Agency of Canada's Travelling Public Program, the New South Wales, Australia Ship Sanitation Program, and the Caribbean Public Health Agency. I also routinely engage with international public health agencies, cruise lines, equipment manufacturers, shipyards, and public health consultants on matters relating to maritime public health.

6) Based on my years of experience with the VSP, I am familiar with the cruise ship industry's policies and practices to mitigate onboard illnesses and their response when outbreaks of illness occur on board cruise ships. VSP data shows that in the past 10 years (2009-2019), out of 2,338 public health inspections of cruise ships in U.S. waters, approximately 75 ships (3%) received a failing inspection score of 85 or below out of 100 points. Additionally, 140 ships (6%) received close to failing scores of between 86 and 89. These low and failing scores occurred despite the VSP's issuance of an Operations Manual that outlines minimum public health and

sanitation standards for cruise ships in U.S. waters, and VSP conducting six 2.5-day public health training courses per year for cruise ship managers and supervisors.

7) Between 2012 and 2019, there were 148 onboard outbreaks of acute gastroenteritis (AGE) cases (defined as when a cumulative percentage of AGE cases reaches 3% among passengers or 3% among crew) on cruise ships in U.S. waters and there were 100 onboard elevations of AGE cases (defined as when a cumulative percentage of AGE cases reaches 2% among passengers or 2% among crew, but not 3%). These elevations and outbreaks required VSP involvement and action, which ranged from remote monitoring and supervision of the cruise ship operator's response to an onboard, field response by VSP. Thus, even in regard to a well-understood, documented, and researched public health phenomenon on cruise ships, for which the cruise ship industry receives extensive instruction, training, and monitoring, breakdowns in cruise ship operators' health and safety protocols can be expected to occur.

8) Upon information and belief, on or about 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.

9) In January 2020, as part of its Coronavirus emergency response efforts, the CDC Emergency Operations Center created the Cruise Ship Task Force (CSTF) to manage the international *Diamond Princess* COVID-19 humanitarian crisis. The U.S. Government's response to this humanitarian crisis included, among other things, the repatriation and subsequent 14-day quarantine at U.S. Department of Defense facilities in Texas and California of approximately 329 U.S. citizens.

10) The CSTF was additionally tasked to respond to an increasing number of COVID-19 cruise ship outbreaks that were occurring both domestically and internationally. The CSTF, along with the U.S. Coast Guard and other components of the U.S. government, assisted in the emergency evacuation of over 40 cruise ships, aiding more than 260,000 passengers to safely disembark. After the conclusion of these operations, the CSTF was disbanded in April 2020 and superseded by the Maritime Unit, which is part of CDC's COVID-19 Global Migration Task Force (GMTF).

11) GMTF, as part of CDC's COVID-19 response, is composed of individual units that develop evidence-based international and domestic travel recommendations; protect the health of U.S.-bound travelers arriving at U.S. air, sea, and land ports of entry; coordinate contact investigations for ill or exposed travelers; provide technical assistance to cruise ships to prevent and control the spread of COVID-19 among passengers, crew, and shoreside communities; and develop and implement overseas and domestic guidance to prevent and mitigate COVID-19 in U.S.-bound refugees, immigrants, migrants, and globally mobile populations.

12) Because of VSP's vast experience on cruise ships and my role in managing the disinfection and crew quarantine of another Princess cruise ship, the *Grand Princess,* discussed below, I was asked to lead the CDC Maritime Unit in support of CDC's COVID-19 response on cruise ships. I have been leading the Maritime Unit since April 15, 2020.

13) In my capacity as Maritime Unit Lead, I oversee a staff of between 25 and 30 CDC personnel, including medical doctors, epidemiologists, laboratorians, public health officers, environmental health officers, health communicators, and administrative staff. These staff compose the Maritime Unit's various teams, which, among other duties, gather and compile epidemiologic and other data; review laboratory test results and assist cruise ship operators in building laboratory capacity; assist cruise ship operators with embarking and disembarking crew and responding to crew illnesses onboard; create COVID-19 surveillance systems for cruise ships; plan for future cruise ship operations; and assist with communications to media, interagency partners, cruise industry, and the public.

14) Since HHS/CDC's original No Sail Order, signed on March 14, 2020, CDC has worked to control COVID-19 on cruise ships that remained at sea, while protecting against further introduction and spread of COVID-19 into U.S. communities. As of April, 28, 2021, CDC has expended an estimated 100,000 person-hours on the cruise ship COVID-19 response since March 14, 2020—in addition to the thousands of hours invested by other HHS components, other U.S.

government agencies, and state and local authorities. CDC continues to have regular conversations by phone and email with cruise lines, often daily.

15) I additionally liaise with and provide updates to GMTF leadership, and collaborate with international, federal, state, and local partners. I also work closely with CDC's international maritime public health partners, who share concerns regarding the restart of cruise ship operations during a pandemic.

16) During February 7–23, 2020, the largest cluster of COVID-19 cases outside mainland China occurred on the *Diamond Princess* cruise ship, which was quarantined in the port of Yokohama, Japan. A scientific article published in the Journal of Travel Medicine by Rocklöv et al. later 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.[1] 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.

17) During February 11–21, 2020, the *Grand Princess* cruise ship sailed roundtrip from San Francisco, California, making four stops in Mexico (voyage A).

[1] 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.

Approximately, 1,111 crew and 68 passengers from voyage A remained on board for a second voyage that departed San Francisco on February 21 (voyage B), with a planned return on March 7. On March 4, a clinician in California reported two patients with COVID-19 symptoms who had traveled on voyage A, one of whom had positive test results for SARS-CoV-2. CDC notified the cruise line, which began cancelling group activities on voyage B. Additional cases of COVID-19 among persons who traveled on *Grand Princess* voyage A, but not on voyage B, were subsequently identified. One death was also reported at that time. On March 5, a U.S. Government response team was transported by helicopter to the ship (which was still on voyage B) to collect specimens from 45 passengers and crew with respiratory symptoms for SARS-CoV-2 testing; 21 (46.7%), including two passengers and 19 crew, had positive test results. The two *Grand Princess* voyages (voyages A and B) were ultimately associated with approximately 164 confirmed COVID-19 cases, including nine deaths.

18) I, along with other staff from VSP and WFEHSB, deployed to California to support the *Grand Princess* disinfection and crew quarantine and to conduct environmental assessments. Beginning on March 7, staff from WFEHSB deployed for a total of 112 person-days (i.e., number of personnel times number of days) to: support CDC's infection control team and international cruise ship team in the COVID-19 response; review ship disinfection and crew quarantine procedures and oversee implementation; collect environmental samples before and after disinfection to evaluate effectiveness; and conduct an environmental assessment of the ship,

including checking food operations, potable water, pest management, ventilation, and waste management.

19) A 14-day onboard quarantine for all *Grand Princess* crew members potentially exposed to the virus that causes COVID-19 began on March 21, 2020 and ended on April 4, 2020. I led a team of WFEHSB staff which boarded the ship daily to monitor implementation of the quarantine plan. During the *Grand Princess* mission, team members coordinated with a variety of agencies shoreside, including: Disaster Medical Assistance Teams, U.S. Public Health Service, U.S. Customs and Border Protection, the Port of San Francisco, U.S. Department of Health and Human Services/Assistant Secretary for Preparedness and Response, U.S. Department of State, U.S. Coast Guard, local law enforcement, and San Francisco Bar Pilots Association.

20) The COVID-19 outbreak onboard the *Grand Princess* cruise ship demonstrates the enormous logistical, operational, and financial burdens involved in placing just one cruise ship under quarantine. More than 2,000 U.S. persons were placed under federal quarantine on four U.S. Department of Defense facilities for 14 days. Persons requiring medical attention for other conditions or for symptoms consistent with COVID-19 were evaluated, tested for SARS-CoV-2 infection, and hospitalized if indicated. Repatriation flights for foreign nationals were organized by several governments in coordination with U.S. federal and California state government agencies. Foreign crew completed quarantine on board this ship under the supervision of the cruise company with technical assistance provided by public

health experts. Due to transfers of crew members from the *Grand Princess* to other ships before the voyage was halted, three other ships were ordered to return to port and were temporarily detained.

21) Between February and April 2020, CDC issued 27 separate notifications of COVID-19 outbreaks on cruise ships to international, state, and local health departments. This represents almost 11,000 cruise ship passengers who required contact tracing. Contact tracing is used by health departments to slow the spread of COVID-19 by letting people know that they may have been exposed and that they should self-quarantine or isolate if symptoms develop.

22) These approximately 11,000 cruise ship passenger contacts are significantly more than the nearly 3,000 contacts identified from flight investigations during the same timeframe. Medical evacuation efforts necessitated by these outbreaks required resource-intensive operations that involved multiple small boats to ferry contagious crew and passengers to shore and high levels of coordination between Federal, State, and local public health, maritime, and other governmental authorities.

23) These response efforts drew valuable resources away from the immense Federal, State, and local efforts to contain and mitigate the spread of COVID-19. State and local public health officials further stated that they faced an increasing burden supporting cruise ships attempting to make port with ill passengers or crew and struggled to repatriate passengers and crew while also protecting the limited medical assets available to their communities. The intensive care requirements for infected passengers and crew in need of life-saving critical care also greatly stressed

an already overtaxed healthcare system that at the time was facing shortages of masks, test kits, beds, and ventilators needed to respond to COVID-19.

24) Cruises vary in size with larger cruises involving populations of more than 6,000 passengers and crew who move in closed and semi-closed settings that facilitate transmission of COVID-19. Cruises include frequent events that bring passengers and crew close together, including group and buffet dining, entertainment events, and excursions. Cruise ship cabins are small, increasing the risk of transmission between cabinmates. Crew closely quarter in crowded spaces for eating and sleeping. Infection among crew members may lead to transmission on sequential cruises on the same ship because crew members may continue to work and live onboard the ship from one cruise to the next. Crew from one ship may in turn serve onboard multiple different ships for subsequent voyages, which can amplify transmission.

25) Travelers from different countries brought together in the often crowded, enclosed and semi-enclosed environments onboard ships can facilitate the spread of person-to-person, foodborne, or waterborne diseases. The most frequently reported cruise ship outbreaks involve respiratory infections, AGE infections (such as norovirus), and vaccine-preventable diseases other than influenza, such as varicella (chickenpox). Outbreaks on ships can be sustained for multiple voyages by transmission among crew members who remain onboard or by persistent environmental contamination.

26) Due to this increased transmission risk 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 Fed. Reg. 16628). The CDC's March 14, 2020, Order followed a March 13, 2020, announcement by the 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. 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.

27) Between March 1 and April 15, 2020, confirmed COVID-19 outbreaks were reported on approximately 43 additional cruise ships with passengers including the *Costa Magica*, *Costa Favolosa*, *Celebrity Eclipse*, *Disney Wonder*, *Holland America Zaandam*, and *Coral Princess*. *Costa Magica* and *Costa Favolosa* reported at least 110 ill crew members, which required emergency medical evacuations, in coordination with U.S. Coast Guard and public health personnel. Six infected crew members on the *Magica* and seven from the *Favolosa* required emergency medical evacuations for life-critical care. The *Zaandam* cruise ship reported illness consistent with COVID-19 in at least 269 persons onboard, including 11 deaths with 10 deaths among passengers (one for non-COVID-19 related reasons). The *Eclipse* returned to San Diego, California, after being denied entry into other ports, with local health departments

left to deal with approximately 108 confirmed cases and 125 suspect cases. The *Disney Wonder* experienced a large outbreak of 292 cases, including 260 crew members and 32 passengers (including 3 passenger deaths).

28) These medical evacuation efforts were resource-intensive operations that required use of small boats to transport contagious crew to shore, U.S. Coast Guard air medical evacuation, and high levels of coordination between international, Federal, State, and local public health, maritime, and other governmental authorities. Moreover, safely evacuating, triaging, and repatriating cruise ship passengers and crew involved complex logistics, incurred financial costs at all levels of government, and diverted resources away from larger efforts to suppress or mitigate COVID-19.

29) 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, effective on April 15, 2020 (85 Fed. Reg. 21004).

30) Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique—that is, permission to enter U.S. ports, disembark, and operate under certain conditions—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.

31) 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. CDC also established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships by requiring 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 (85 Fed. Reg. 62732).

32) 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 Fed. Reg. 44085), and *Third Modification and Extension of No Sail Order and Other Measures Related to Operations* on September 30, 2020, (85 Fed. Reg. 62732). This last order, among other things, continued to suspend passenger operations on board cruise ships through October 31, 2020, pending cruise lines' submission of their COVID-19 response plans.

33) On October 30, 2020, CDC issued a *Framework for Conditional Sailing Order* (85 Fed. Reg. 70153). The CSO takes a phased approach to resuming cruise ship passenger operations in U.S. waters. There are four phases to the CSO: mass crew testing and lab capacity building for future travelers (passengers and crew) (Phase 1); preparation for simulated voyages (Phase 2A) and simulated voyages (Phase 2B);

applying for a COVID-19 Conditional Sailing Certificate (Phase 3); and restricted passenger voyages (i.e., revenue voyages with public health precautions in place to mitigate COVID-19 spread) (Phase 4).

34) This phased approach was adopted based on the best available science including epidemiology, surveillance data obtained from weekly submission of the EDC report from cruise ships, advancements in testing, laboratory analysis, and drug therapeutics. CDC also incorporated lessons learned from its review of cruise ship operators' No Sail Order (NSO) response plans submitted in response to the April 15, 2020 NSO Extension, passenger and crew disembarkations and repatriations that occurred early in the pandemic, and attempts to prematurely restart cruises in foreign jurisdictions.

35) In drafting the CSO, CDC carefully considered public comments submitted as part of a Request for Information (RFI) published in the Federal Register on July 20, 2020. That RFI, issued in conjunction with the July 2020 extension of the NSO, sought comment on 26 questions, many with multiple subparts, concerning cruise ship planning and infrastructure, resumption of passenger operations, and related topics (85 Fed. Reg. 44083). The 60-day comment period ended on September 21, 2020 and nearly 13,000 comments were received.

36) 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.

37) The State of Alaska submitted comments that among other things stressed the need for cruise ship operators to work with local authorities and have in place prearranged shoreside contracts for housing, transportation, and other services for passengers and crew requiring evacuation from cruise ships. The Florida Ports Council, the Chief Executive and Port Director's Office for Port Everglades, and President and CEO of Tampa Port Authority, similarly submitted comments stressing the need for cruise ship operators to develop health and safety protocols relating to the use of local medical facilities and the safe evacuation and transportation of potentially infected cruise ship passengers in way that does not burden local resources. See Exhibit A (selected comments).

38) Approximately 74% of RFI respondents indicated that cruise ship passenger operations should immediately resume despite the surging pandemic, while 26% of respondents supported continuing the No Sail Order. However, about 98% of respondents supported cruise ship operators denying boarding to passengers with COVID-like illness or confirmed COVID-19 infection. Approximately 65% of respondents also supported denying boarding to passengers with known COVID-19 exposure in the previous 14 days before embarkation. A majority of respondents (74%) additionally 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.

39) While CDC bases its public health determinations on the best available science and not on public opinion, public responses demonstrated a willingness to accept shipboard and shoreside measures to mitigate the risk of transmitting COVID-19 onboard cruise ships.

40) In drafting the CSO, CDC also considered alternatives. 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 and additional outbreaks would further burden ports and local communities.

41) For example, as late as July 2020, after the suspension of cruise ship operations in the United States in March, outbreaks on board cruise ships occurred in foreign countries that allowed cruise ships to resume operations. Upon information and belief, on the Hurtigruten cruise ship *MS Roald Amundsen*, 41 crew members and 21 passengers were confirmed to have COVID-19 after two voyages occurring between July 17–24 and July 25–31 in Norway. The ship had 209 passengers on the first voyage and 178 on the second. The cruise ship operator permitted passengers to disembark on July 31, before the announcement of the outbreak, potentially spreading the virus to dozens of towns and villages along Norway's western coast and setting off an effort by public health authorities to trace and locate the nearly 400 potentially exposed passengers. The protocols adopted by the Hurtigruten included new sanitation measures, elimination of self-serve buffet

dining, implementation of onboard social distancing procedures, operating at 50% capacity, a preboarding health questionnaire, and restricted shore excursions. Accordingly, simply relying on cruise ship operators to implement their own COVID-19 health and safety protocols was not seen as optimal as a careful, phased approach to resuming cruise ship passenger operations.

42) Another alternative considered was continuing to issue "No Sail Orders" as occurred between March 14 and September 30, 2020. However, this alternative was found to be less optimal than the CSO's phased approach, which takes into account the evolving state of the pandemic—in the United States and worldwide—and allows CDC to incorporate the best available science including advancements in vaccines and drug therapeutics. This approach also allowed cruise ship operators an opportunity to demonstrate the effectiveness of their health and safety protocols at mitigating COVID-19 through a government-supervised process.

43) In drafting the CSO, CDC further considered efforts by cruise ship operators to advance their public health response to COVID-19. For example, under the co-chairmanship of former Secretary of Health and Human Services 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" (HSP) of subject-matter experts from a variety of disciplines.

44) CDC sent two observers to the HSP meetings who, while not acting as participants, engaged in dialogue, and exchanged information with other subject-matter experts. The CDC Maritime Unit reviewed the documents from these

meetings and the HSP's final recommendations. While the Maritime Unit agreed that some approaches identified in the HSP's recommendations, including contact tracing, sanitation, in-cabin medical visits, and education of passengers and crew about COVID-19, could help improve traveler comfort and public health outcomes, it found them inadequate to sufficiently mitigate the introduction, transmission, and amplification of COVID-19 on cruise ships and to U.S. communities. Accordingly, more emphasis was needed on actions to mitigate potentially infected travelers from boarding ships in the first instance so that fewer government resources would be needed from local, state, and federal agencies—as well as onshore medical facilities—to manage cases and outbreaks.

45) In drafting the CSO, the Maritime Unit agreed with the HSP that a "phased approach" to resuming passenger operations was needed, including simulated voyages. In addition, the Maritime Unit agreed with the panel's recommendation that cruise ship operators plan for "small-, moderate-, and large-scale debarkation scenarios in advance of cruising."

46) Phase 1 of the CSO consisted of testing and additional safeguards for crew members and the building of additional laboratory capacity by cruise ship operators to test future passengers. The CSO originally required that cruise ship operators with ships in U.S. waters complete this first phase by December 29, 2020 (60 days after the effective date of the CSO). Cruise ship operators were expected to collect clinical specimens for SARS-CoV-2 testing from all crew currently onboard their cruise ships

and arrange for the transportation and testing of those specimens at a shoreside laboratory facility.

47) To assist cruise ship operators in meeting the requirements of Phase 1 of the CSO, CDC's Maritime Unit established a Laboratory Team with four to five full-time experts in multiple disciplines led by laboratory subject matter experts. This Laboratory Team and its subject matter experts met with cruise line and manufacturer representatives to discuss equipment supply concerns and worked with individual cruise lines to address technical issues, provided consultations regarding which testing instruments to procure, and helped them identify shoreside laboratories and laboratory equipment manufacturers. The Maritime Unit's Laboratory Team has conservatively expended over 5,000 personnel-hours on these efforts.

48) By December 29, 2020, cruise ship operators with ships in U.S. waters, in coordination with CDC, were also expected to implement onboard testing capabilities to be able to test all symptomatic travelers (crew and future passengers) and their close contacts for SARS-CoV-2. However, cruise ship operators informed CDC that, because of supply issues for procuring onboard laboratory equipment, not all cruise ships operating in U.S. waters were able to procure necessary equipment. Accordingly, on December 23, 2020, CDC announced that it would exercise enforcement discretion for Phase 1 of the CSO to allow cruise ship operators additional time to comply with the crew testing and lab capacity requirements.

49) As of April 26, 2021, 95% of cruise ships under the jurisdiction of the CSO (56 out of 59 cruise ships) have performed mass screening testing of all crew.

Additionally, 97% (57 out of 59 ships) have had their plans for onboard point-of-care laboratory assays, instruments, and reagents approved by CDC. However, while 92% (54 out of 59 ships) have procured testing supplies as specified by the manufacturer of their testing instruments, only 80% (47 out of 59 ships) have had those testing instruments installed on their ships. Cruise lines have also reported that most onboard medical staff have been trained on specimen collection and the use of their onboard testing instruments. Accordingly, as of April 26, 2021, 80% (47 out of 59 ships) have fully completed Phase 1, the largest limiting factor being installation of onboard testing instruments and are ready to proceed to Phase 2.

50) On April 2, 2021, CDC released the technical instructions for Phase 2A of the CSO. The approximately 3-month delay between December 29, 2020 (the date by which most cruise ship operators were expected to complete mass crew testing) and April 2, 2021 (the date the Phase 2A guidance was issued), can be attributed to the additional time needed for cruise ship operators to conduct mass crew testing and procure testing instruments and supplies for future embarkations of passengers and crew. Delay can also be attributed to the need to draft the additional new guidance, consult with federal and local partners, and the change in Administration on January 20, 2021, which involved a change in CDC and other federal leadership, as well as the need to advise and brief these individuals on the history and workings of the CSO.

51) During Phase 2A, cruise ship operators will work to establish agreements at ports where they intend to operate that must be approved by port authorities and

local public health authorities. These agreements will ensure that the necessary infrastructure is in place in the event of an outbreak of COVID-19 onboard cruise ship operators' ships, including healthcare capacity and housing to isolate infected people and quarantine those who are exposed. It must also include a plan and timeline for vaccination of cruise ship crew and seaport personnel prior to resuming passenger operations. Under these agreements, port authorities and local public health authorities may determine the maximum number of ships and travelers permitted to operate out of their ports considering their medical and other capacity in the event of a significant outbreak of COVID-19.

52) On April 28, 2021, CDC issued a "Dear Colleague" letter (Exhibit B) to cruise line industry representatives based on the results of twice weekly meetings with those representatives and other federal agencies. This letter provides important clarifications regarding CDC's previously issued Phase 2A technical instructions and greater flexibility regarding how cruise ship operators choose to comply with CDC's requirements, including through entering into multi-jurisdictional port agreements instead of agreements with individual port jurisdictions. It also reiterates the CDC's commitment to the phased resumption of passenger operations around mid-summer.

53) The intent of Phase 2A is to provide port and local health authorities with an opportunity to determine to what extent they wish cruise ship travel to resume in their own communities. Phase 2A does not impose requirements on port and local health authorities, but rather requires the cruise ship operator to demonstrate that they have conferred with these authorities prior to conducting a simulated voyage or

engaging in restricted passenger voyages. Port and local health authorities are under no obligation to deliberate or enter into a Phase 2A agreement with a cruise ship operator. Under the recent "Dear Colleague" letter, if a port or local health department desires to enter into a Phase 2A agreement with a cruise ship operator but concludes that it lacks sufficient medical and housing capacity in the event of an outbreak, the cruise ship operator would be authorized to enter into a "multi-jurisdictional" agreement with multiple port authorities to ensure sufficient capacities are in place provided that all relevant jurisdictional authorities agree to this arrangement.

54) In developing the Phase 2A technical instructions, CDC consulted with representatives from international, federal, state, and local partners, including European Union's Healthy Gateways Maritime Transport team, World Health Organization's Border Health Risk Dissemination Unit, Caribbean Public Health Agency, U.S. Coast Guard, Florida Department of Health, Alaska Department of Health and Social Services, and Port Canaveral, Florida.

55) During these discussions, port and local health authorities—including Florida, Alaska, California, Washington, and Louisiana—expressed the following concerns: 1) unease over cruise ship operators introducing COVID-19 into local communities by prematurely resuming cruise ship passenger operations during an ongoing pandemic; 2) need for cruise ship operators to share individual patient data with local public health partners to ensure timeliness and transparency; 3) estimate of the approximate number of persons embarking and disembarking on any given day for

community planning purposes; 4) routine testing of crew and port partners to protect the public health; 5) need for advance agreement on all aspects of medical care (including disembarkation, transportation, and facilities); and 6) cruise ship industry identification of housing facilities for travelers who need to be isolated and quarantined. Lastly, partners stressed the need to have these details in writing and agreed to by all parties.

56) The Maritime Unit includes a team of laboratory subject matter experts to keep up to date on the latest testing advancements. During initial phases of the CSO, antigen testing was not recommended because vaccines were not yet available and this testing is more likely to miss cases of SARS-CoV-2 infection (i.e., lower sensitivity) when compared to reverse transcription polymerase chain reaction (RT-PCR) testing. CDC has several studies being performed that compare antigen screening testing to RT-PCR and, sometimes, viral culture. Preliminary data has shown that, when used for screening purposes, antigen testing is both less sensitive (i.e., more false negatives) and less specific (i.e., more false positives) than when used for diagnostic purposes (i.e., for symptomatic or exposed persons).

57) Because the cruise environment represents a high-risk, residential congregate setting, the most accurate (i.e., most sensitive and specific) test should be used during Phases 1 and 2 of the CSO. However, CDC's April 28, 2021 "Dear Colleague" letter (Exhibit B) clarifies that based on lessons learned from the initial phase of crew testing, advancements in laboratory testing in the U.S., and greater availability and

more widespread use of vaccines, the Maritime Unit will be updating technical instructions to include all forms of viral testing, including antigen.

58) In the next phase (2B), simulated (trial) voyages will allow cruise ship operators, crew, and seaport personnel to practice their COVID-19 operational procedures with volunteers simulating the role of passengers before ships sail with paying passengers. Simulations will help cruise ship operators to identify practices that are successful at mitigating COVID-19 on board their ships, as well as any deficiencies in their health and safety protocols that need to be addressed prior to resuming passenger operations. Phase 3 will include an application process to certify ships for restricted passenger voyages. On May 5, 2021, the documents for Phase 2B and Phase 3 were finalized, posted to CDC's website,[2] and made available to cruise ship operators (Exhibits C, D). These documents include:

- Eligibility criteria and requirements for the simulated voyage;
- Guidance for CDC inspections of cruise ships during simulated and restricted passenger voyages; and
- Operational procedures to assist cruise ship operators in mitigating the risk of spreading COVID-19, including requirements and recommendations on prevention measures, surveillance for COVID-19 on board, laboratory testing, infection prevention and control, face mask use, social distancing, passenger interactive experiences, and embarkation and disembarkation procedures.

[2] https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html and https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html

With the release of this guidance, cruise ship operators have the information they need to move through Phases 2 and 3 and ultimately commence passenger operations.

59) COVID-19 vaccines will play a critical role in the safe resumption of passenger operations and plans to vaccinate crew and seaport personnel are an important part of returning to passenger operations. However, while some cruise lines have publicly stated that they intend to require passengers to be vaccinated, others have announced that they do not plan to require vaccinations or have announced no plans. Some passengers, notably children, are also not currently eligible to get a COVID-19 vaccine. Furthermore, cruise lines have not indicated how they intend to seek and confirm information about passenger vaccinations. CDC intends to update testing and quarantine requirements for passengers and crew to closely align with CDC's guidance for fully vaccinated and not fully vaccinated persons.

60) As part of its ongoing discussions with cruise line representatives, CDC has reviewed a purported vaccination statement submitted by these representatives outlining the industry's proposed vaccination goals. (Exhibit E) Upon information and belief, cruise lines are in discussion with several Governors' offices in States in which cruise ship operators plan to operate, for such states to provide the necessary supply of surplus vaccine to vaccinate crew, and are working to arrange a mutually agreed path forward. While CDC supports States using surplus vaccine supplies to vaccinate cruise ship crew, potential barriers to this plan exist. This includes perceptions of prioritizing foreign cruise ship workers over States' residents and other

competing priority groups; logistics and time involved in administering a 2-dose vaccine with a 21- to 28-day wait in between doses; whether both doses will be administered by the same jurisdiction; and unresolved issues regarding whether cruise ship operators will reimburse States for cost of the vaccines and their administration. While the Johnson & Johnson vaccine is a one dose vaccine that could expedite vaccination of cruise ship crew, there is high demand for use of this vaccine among other population groups, including the unhoused, college students, and other difficult to reach populations.

61) Furthermore, based on previous experience relating to vaccination for the influenza vaccine, a vaccine that is inexpensive and widely available, there is reason to doubt that many cruise ship operators will be able to fully vaccinate crew. In discussions with the Maritime Unit, senior cruise line executives have pointed to voluntary influenza vaccination rates for crew being an indicator for expected voluntary COVID-19 vaccination rates. CDC analyzed the influenza vaccination rates among cruise ship crew from the 63 influenza outbreaks on cruise voyages between 1/1/2019 and 3/31/2020. Eighteen (29%) of those outbreak voyages had crew vaccination rates of less than 50%. The average crew vaccination rate among those voyages was 61%. This is despite CDC's online guidance for cruise ships on influenza outbreak management and outreach to individual cruise ships that meet outbreak status. These percentages are concerning due to the high vaccine coverage needed to prevent COVID-19 outbreaks.

62) Preliminary CDC modeling data also indicates that to avoid significant outbreaks of COVID-19, cruise ship operators will need to conduct voyages with a high percentage of vaccinated passengers and crew, use a highly effective vaccine, test all passengers and crew for COVID-19 on their day of embarkation, and immediately quarantine newly-embarking crew for 14-days.

63) If a cruise ship has crew that originate from a community with a medium prevalence of COVID-19 and 50% of those crew are fully vaccinated for COVID-19 with a vaccine that is 90% effective, the modeling data estimates that the crews' risk of introducing COVID-19 onto the ship has been reduced by 99.9%. However, this model assumes that all crew are tested for COVID-19 on their day of embarkation and immediately enter a 14-day quarantine. Under this model, most of this risk reduction can be attributed to day-of-embarkation testing and 14-day quarantine. Absent the protection afforded by the 14-day quarantine, a rate of vaccination significantly higher than 50% would be needed to achieve an equivalent level of COVID-19 risk reduction. Based on wider vaccine availability, CDC does not expect to require a 14-day quarantine of embarking crew once cruise ship operators resume restricted passenger voyages.

64) If passengers originate from a community with a medium prevalence of COVID-19 and 50% of those passengers are fully vaccinated for COVID-19 with a vaccine that is 90% effective, the modeling data estimates that the passengers' risk of introducing COVID-19 onto the ship has only been reduced by 62.8%. Under this model, most of this risk reduction can be attributed to vaccination and day-of-

embarkation testing. This model assumes that a 14-day quarantine of all passengers would be impractical and thus not occur.

65) This model additionally estimates 4 cases of COVID-19 infections will be introduced onto a ship sailing with 2,000 passengers, despite day-of-embarkation testing, and that additional transmission of COVID-19 on this ship will occur 67% of the time. There will be an average of 6 additional infections by day 4 of the voyage. In some situations, using the same model parameters, there can be up to 16 additional infections by day 4 of the voyage. This is based on a model of 2,000 passengers and 1,000 crew, a voyage duration of 7 days, and a reproductive value (R_0) of 5.

66) CDC continues to evaluate the impact of vaccinations. This includes how long vaccines protect individuals, including older adults, persons with weakened immune systems, or who take immunosuppressive medications. In addition, research is still ongoing regarding how well COVID-19 vaccines keep people from spreading the disease to others. The need for and timing of COVID-19 booster doses have also not been established, although vaccine manufacturers have indicated in recent media reports that there may be a need for a booster vaccine between 6 and 12 months. CDC is still recommending that fully vaccinated people should avoid indoor large-sized in-person gatherings for these reasons.

67) However, based the above referenced CDC modeling data, CDC's April 28, 2021 "Dear Colleague" letter (Exhibit B) indicated that in lieu of conducting a Phase 2B simulated voyage, cruise ship operators' responsible officials, at their discretion,

may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98% of crew are fully vaccinated and submit to CDC a clear and specific plan and timeline to limit cruise ship sailings to voyages where 95% of passengers have been verified by the cruise ship operator as fully vaccinated prior to sailing. Cruise ship operators that chose to do so may proceed directly to Phase 3 and apply for a COVID-19 Conditional Sailing Certificate to resume passenger operations.

68) CDC continues to evaluate how well vaccines protect against emerging SARS-CoV-2 variants and how these variants will affect infection prevention and control recommendations. An emerging variant of interest requires additional laboratory and epidemiological investigation to assess how easily the virus spreads to others, the severity of disease, the efficacy of therapeutics, and whether currently authorized vaccines offer protection. Early data show the vaccines currently available in the United States may work against some variants but could be less effective against others.

69) Vaccination of cruise ship crew continues to be a concern for the resumption of passenger operations. Cruise ship crew are primarily foreign nationals and many of their countries of origin (including the Philippines, Indonesia, and India) have very low rates of vaccination for COVID-19. Upon information and belief, Royal Caribbean Cruise Lines have halted their hiring of foreign nationals from India based on surging rates of COVID-19 in that country. Additionally, the efficacy of non-FDA authorized and non-WHO listed vaccines that are currently available to foreign-based crew members in their home countries have not been fully demonstrated.

70) Upon information and belief and based on discussions with cruise ship operators, at this time most plan to encourage crew to be vaccinated on a voluntary basis as vaccines become more widely available. This is because vaccines are currently not commercially available and can only be obtained through government resources. Recent media reports confirmed that the cost to governments of the two-dose COVID-19 vaccines currently authorized for use in the U.S. cost between $19.50 to $37 per dose ($39 to $74 for the complete series). Vaccine manufacturers have noted in media reports that they may increase these prices when they offer the vaccine commercially.

71) By comparison, per CDC's Vaccine Price List, the adult influenza vaccine costs between $17.89 to $26.39 per dose in the private sector. The CDC Vaccine Price Lists provides current vaccine contract prices and lists the private sector vaccine prices for general information. Contract prices are those for CDC vaccine contracts that are established for the purchase of vaccines by immunization programs that receive CDC immunization cooperative agreement funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories). Private providers and private citizens cannot directly purchase vaccines through CDC contracts. Private sector prices are those reported by vaccine manufacturers annually to CDC. Based on the above information, cruise ship operators may face a significant cost when vaccinating their own crew with commercially available vaccines.

72) Even when travelers are vaccinated, protective public health measures—such as testing, mask use, and physical distancing—will still be important because of concern over variants and continuing research regarding how well vaccines provide full protection against the virus, particularly in regards to older adults or those who are immunosuppressed.

73) CDC acknowledges that it is not possible for cruising to be a zero-risk activity for spread of COVID-19. While cruising will continue to pose some risk of COVID-19 transmission, CDC is committed to ensuring that cruise ship passenger operations are conducted in a way that protects crew members, passengers, and port personnel, particularly with emerging COVID-19 variants of concern. This is consistent with CDC's statutory obligations to "prevent the introduction, transmission, and spread of communicable diseases" under 42 U.S.C. § 264.

74) CDC is further committed to working with the cruise industry and seaport partners to resume cruising following the phased approach outlined in the CSO. In support of that goal and to ensure transparency, CDC, DHS, and U.S. Department of Transportation senior leadership have recently hosted multiple meetings with key cruise industry leaders. The objective of these meetings is to discuss top priority issues of the cruise industry, including the impact of vaccines and other scientific developments since the Order was issued in October 2020. This goal aligns with the desire expressed by many major cruise ship operators and travelers for the resumption of passenger operations in the United States by mid-summer.

75) It is my professional judgment, based on nearly 20 years of professional experience and the science gathered regarding SARS-CoV-2 transmission, that absent the protections afforded by the CSO's phased approach, allowing cruise ship operators to immediately return to unrestricted passenger travel (i.e., travel subject only to voluntary measures to address the threat of COVID-19) would likely exacerbate and amplify the spread of SARS-CoV-2, the virus that causes COVID-19. Data from CDC's crew surveillance system from November 30, 2020 through April 25, 2021, demonstrates the enormous difficulty in identifying and preventing COVID-affected persons from boarding cruise ships. Out of 131 crew cases identified on board cruise ships, 43% (56) were identified during the initial 14-day ship quarantine mandated by CDC. This shows the difficulty of attempting to prevent COVID-19 cases from boarding ships through pre-embarkation testing plus exposure and symptom screening.

76) Cruise ships, unlike other forms of voluntary recreation or travel such as theaters, amusement parks, and aviation, present a unique setting that is particularly conducive to transmission of the virus that causes COVID-19. Cruise ships bring diverse passenger and crew populations together in close proximity for many days, leading to potential transmission of respiratory illness. Cruise ships also have a high population density on board, which are typically more densely populated than cities or most other living situations. Factors that facilitate the significantly heightened spread of SARS-CoV-2 on cruise ships may include:

- Comingling of travelers from multiple geographic regions.

- Closed nature of the cruise ship environment.
- Older passenger population who frequently make cruise voyages and are at increased risk for serious complications.
- Crew members who transfer between ships and voyages can perpetuate transmission across multiple voyages and ships.
- The passenger population represents an older demographic, some of whom have underlying medical conditions that put them at higher risk for severe complications of COVID-19.
- Quarantine and isolation measures are difficult to implement effectively onboard a cruise ship and only occur after an infection has already been identified.

77) While CDC has not prohibited persons from flying overseas to engage in cruise ship travel, CDC has recommended that all people avoid travel on cruise ships, including river cruises, worldwide. Furthermore, while CDC does not have data indicating what percentage of airline travelers may choose to go oversees to engage in cruise travel contrary to CDC's recommendations, experience and common sense suggests that this number is significantly less than those passengers who would choose to cruise from a port in the United States if cruise ship operations were to immediately resume outside of the CSO's phased approach. CDC also lacks the ability to track the itineraries of individual travelers to know which travelers may choose to go on a cruise after flying overseas.

78) While some cruise ship operators have claimed to have successfully engaged in cruising with hundreds of thousands of passengers in foreign markets, including Asia, with no or only limited transmission of COVID-19, this is not an equivalent comparison to cruising in the United States. Many of these claims are based on the country of Singapore—a small island nation with a consistently low prevalence of SARS-CoV-2 infection and federal authority over its travel industry. Since November 2020, Singapore has experienced only a handful of locally transmitted new cases each day (between zero and five cases/day). Its cruise voyages have been open only to Singapore residents on itineraries that only port within Singapore and at a reduced capacity. Ironically, this nation's Tourism Board has employed similar regulatory measures to what CDC has detailed in the CSO, including a "Health Safety Framework" and a "Cruise Safe Certification" which all cruise operators must obtain before they can sail (and requires mandatory testing, physical distancing, and disease response planning). The low prevalence of disease in Singapore combined with its federally mandated protocols and assistance would be analogous to those measures detailed in the CSO when accompanied by a highly vaccinated cruise population in the United States.

79) Similarly, some cruise ship operators have claimed to have successfully engaged in cruising in the Europe. However, these cruises have not been without incident. From September to November 2020, media sources reported several outbreaks occurred on European river cruise ships where approximately 100 persons were infected, including 8 travelers on CroisiEurope's *Vasco da Gama* cruise ship in

September, 60 passengers on the *MS Swiss Crystal* and 13 travelers on the *MS Vista Serenity* in October, and 10 crew members on the *MS Thurgau Chopin* in November. Many other river cruise voyages in Europe were cancelled due to the threat of COVID-19.

80) From July 2020 to February 2021, outbreaks were reported on European non-river cruise ships with over 100 persons infected, including 71 travelers on Hurtigruten's *MS Roald Amundsen*, 10 crew on AIDA cruise line, and 5 crew on the Mein Schiff 1 in July; three travelers on the *MS Finnmarken* in September; 13 travelers on the Le Jacques-Cartier, 8 on the Costa *Diadema*, and 1 on the MSC *Grandiosa* in October. In February of this year, four guests tested positive for COVID on the *Mein Schiff 2*.

81) Furthermore, while the cruise industry has claimed to have successfully prevented the introduction and transmission of COVID-19 on board and into communities in Europe, this claim cannot be substantiated without results from laboratory testing of disembarking passengers or crew and further follow-up with travelers post-cruise. Such testing and follow-up do not occur in these foreign markets. Local and national public health authorities in Europe also do not routinely collect or mandate collection of these data. Unlike in the United States, which has federally-mandated requirements on cruise ships to report illness and death to CDC-staffed Quarantine Stations at major ports of entry, European countries do not have similar systems in place to track cruise ship-related cases or outbreaks. Based on this lack of testing and data collection, potential failures in cruise ship industry protocols

and practices cannot be reliability recognized because cases can only be identified within a community and not linked to a cruise ship exposure.

82) Accordingly, it is my professional judgment based on all the information available to CDC, that it is necessary to continue the phased approach and protections of the CSO to protect the public's health.

83) In accordance with 28 U.S.C. § 1746, I declare, under penalty of perjury, that the above information is true and correct to the best of my knowledge and belief.

Signed this 5th day of May 2021.

_____

Aimee Treffiletti, MPH, REHS (CAPT, USPHS)
Maritime Unit
Global Migration Task Force
Centers for Disease Control and Prevention

EXHIBIT A

Docket No. CDC-2020-0087

Please accept these comments from the State of Alaska (SOA) in reference to Docket No. CDC-2020-0087. As a premier destination for tourists, particularly in the cruise ship space, we are in a unique situation to provide substantive comment on the No Sail Order, as well as the questions posed in this request for information.

In general SOA ascribes to the FEMA paradigm of *"locally executed, state managed, and federally supported."* The same paradigm holds true with respect to the resumption of cruise ship operations in the COVID-19 environment. Cruise ship destination communities and ports of call within Alaska are in the best position to make risk-informed decisions, in a collaborative environment with the operators of cruises ships of all sizes. Since the beginning of the pandemic, Alaskan communities and the SOA Department of Health and Social Services (DHSS) have worked directly with entities such as Cruise Lines International Association and individual cruise line operators to make the best decisions to protect the health and welfare of Alaskans, our visitors, and industry. Alaska is a model for public/private partnerships, and collectively government and industry have a long-standing tradition of robust communications and collaboration.

The effects of the pandemic, including CDC's No Sail Order, have severely impacted the economic and fiscal health of Alaska. We are appreciative of CDC's quick action to minimize the introduction of COVID-19 to our state through cruise ship operations, particularly when little was known about the SARS-CoV-2 virus, methods of transmission, and overall epidemiology. Understanding that Alaska's economy is closely tied to the tourism industry, we agree that the No Sail Order was a prudent decision at the time, and allowed our communities and industry to develop a cohesive understanding of the epidemic and how to mitigate the spread. Just as important was the collective, voluntary actions cruise ship operators of all sizes took, knowing the economic impact, in order to protect our communities. To further illustrate the impact to Alaska, the below information speaks to the overall economic impact of the visitor industry in our state. The most recent data is from a 2017 analysis that can be located at https://www.commerce.alaska.gov/web/ded/DEV/TourismDevelopment/TourismResearch.aspx.

Highlights				
Peak Season Jobs 52,000	Taxes and Revenues $125.6 M	Visitor Spending $2.8 B	Economic Impact $4.5 B	Labor Income $1.5 B

These highlights are not specific to the cruise industry, although in general cruise line operations and associated shoreside activities represent 60% of all summer visitors to the state.

The State, nation, and world have all learned a tremendous amount about the virus, and have worked tirelessly to develop non-pharmaceutical interventions, build healthcare capacity, and fortify communications, with two primary goals in mind: 1. Protect the health and safety of Alaskans and Alaska communities; and, 2. Safely restart the economy in all sectors. We strongly believe that our communities and industry partners are well-positioned to resume cruise ship operations for the 2021 season.

For ease of readability, we have left all questions posed in the original docket below. Where SOA does not have substantive comment, "No Comment" will be noted.

Planning and Infrastructure

1. Given the challenges of eliminating COVID-19 on board cruise ships while operating with reduced crew on board during the period of the April 15, 2020 No Sail Order Extension, what methods, strategies, and practices should cruise ship operators implement to prevent COVID-19 transmission when operating with passengers?
    a. A robust program of crew screening and routine screening testing of crewmembers should be a cornerstone of resuming operations. Alaska has observed a number of cultural or stigma-perception issues with crewmembers of vessels, primarily in the seafood industry, not wanting to report minor or moderate symptoms consistent with COVID-19 disease. Consistent with those observations, cruise line operators should implement rigid, consistent daily symptom and temperature screening of crewmembers, and implement all-hands routine surveillance testing.

       Passenger mitigation operations should be "portal-to-portal" with robust communications and direction provided to passengers beginning with sales and booking, through the sailing, and through the disembarkation and return to home process, and longer as necessary. At this time the SOA requires all travelers into the state, whether tourist, critical infrastructure worker, or resident, to receive at least one PCR test when arriving into the state. That same requirement applies to cruise ship passengers, and we encourage specific requirements, whether federally mandated or through voluntary compliance of cruise ship operators, to require passengers to obtain a PCR test with negative results immediately prior to boarding. As additional test methodologies are approved for use and recommended by CDC, we would support those as well.

       Mitigation efforts should maximize the potential for physical distancing between passenger cohorts and crew. Capacity limitations in order to allow for physical separation of dining and gaming tables > 6', physical barriers where feasible, and staggered dining, excursion, and onboard activities would all assist in maintaining separation. If practicable, cohorting small groups of passengers along with dedicated onboard staff, to create a passenger/crewmember cohort may assist with containing discrete outbreaks to the smallest number possible.

       Robust COVID-positive shipboard response plans should be developed. The SOA and cruise operators have conducted detailed planning, training, and exercising with the United States Coast Guard (USCG) with respect to Mass Rescue Operations. Those preparedness steps should be conducted specifically for COVID-19 outbreaks prior to the resumption of operations. A critical factor in the planning process relates to shoreside medical operations, and non-emergency passenger repatriation operations and planning. Alaska has bolstered the capability and capacity of coastal communities to respond to COVID-19 cases with respect to patient care, testing, forward patient movement, etc., but many Alaskan ports of call still have very limited infrastructure to support a widespread outbreak or repatriation operation. It will be incumbent on cruise line agencies and corporations to have robust surge capacity in place to augment local transportation, emergency medical services, and healthcare capacity. Examples include pre-contracted air charter services for both COVID and non-COVID evacuation or repatriation, case management/passenger services staff, and shore-based logistical services.

       Cruise operators in Alaska should continue to comply with USCG Captain of the Port orders and direction from the CDC Anchorage Quarantine Station and state/local public health officials when COVID is suspected or confirmed to be aboard. Ships operating in Alaskan waters are already well versed and familiar with the *Alaska Multi-Agency*

Maritime Communicable Disease Emergency Response Plan, and we recommend utilizing that plan, and other existing plans where possible, as opposed to new federal plan requirements.

2. How should cruise ship operators bolster their internal public health programs with public health experts and invest in a robust public health infrastructure to ensure compliance with measures to detect, prevent, and control the spread of COVID-19?
    a. Since the beginning of the pandemic and no-sail order, operators have worked closely with industry associations such as the Cruise Line Industry Association and Small Passenger Vessel Association. Those trade organizations have stood up national and international panels of public health experts to assist with overall planning and mitigation efforts. We recommend that those panels continue to monitor the evolving base of knowledge on COVID-19 and the SARS-CoV-2 virus throughout the 2021 season, and continue to revise industry-wide recommendations and guidance to include routine communications with operator companies and their safety, health, and medical teams.

    In addition, cruise line operators should be allowed to adjust shipboard and on-shore protocols on a regional basis, as dictated by local and state public health officials. Due to the unique operating environments within Alaska, it is important that CDC and other federal agencies provide high-level frameworks and guidance, that allow operators to adjust the operational and tactical implementation of mitigation and response measures to the communities they visit in the State. Flexibility at the operator or ship-level is necessary, as there are no consistent mandates or restrictions at all U.S. ports of call, and communities will likely have very specific requirements based on the conditions of the pandemic at the time of sailings.

    Operaters should be encouraged to work collaboratively with state and local officials to plan for multi-operator port calls in communities that can accommodate multiple large cruise ships at a time. The timing of shoreside activities will likely need adjustments in order to minimize the impact to our communities from multiple vessels disembarking on the same day or at the same time.

    Vessel-wide health screening, to include temperature checks, and continuous screening testing of employees should be recommended with periodicity to assist in early containment measures should COVID-19 be identified aboard the vessel. Alaska has responded to real-world outbreaks on vessels in the fishing industry, and strongly believe that continuous screening testing should be accomplished to reduce the overall attack rate of an outbreak aboard the vessel.

    Finally, operators should develop testing, contact tracing, and reporting infrastructure that can be accomplished by the operator, reducing the need to rely on shore-based medical and public health infrastructure to the maximum extent possible. Being able to efficiently share outbreak and testing data with local and state public health officials will be vital in order to assist industry with outbreak response activities.

3. How should cruise ship operators ensure internal public health programs are involved in all levels of decision-making processes relating to passenger and crew operations, crew welfare and mental health, occupational health, food safety, potable and recreational water safety, outbreak prevention and management response, and illness surveillance?
    a. Operators sailing to Alaska should be granted the flexibility to work directly with Alaska -based federal agencies, state, and local officials as they have done historically. This includes regular communications with the Alaska Division of Public Health, CDC Anchorage Quarantine Station, USCG District-17, local government, and local healthcare

providers. Existing protocols and requirements of the *Alaska Multi-Agency Maritime Communicable Disease Emergency Response Plan*, in addition to standard statutory and regulatory requirements should continue to be followed.

4. What is the feasibility of conducting COVID-19 diagnostic testing using FDA-approved or authorized laboratory tests on board a cruise ship?
    a. Fishing industry operators in Alaska are currently exploring the feasibility of conducting on-board FDA-approved or authorized laboratory tests. At this time, we cannot comment on the feasibility since industry has only recently been able to commercially procure diagnostic testing equipment. Alaska supports making FDA-approved or authorized, CLIA-waived testing equipment more commercially available to the private sector. Further, we are hopeful that direct point of care antigen testing will be authorized or approved for use in the maritime environment for both diagnostic and surveillance testing.

a. Should specimens be tested on board or should specimens be collected on board for commercial testing onshore?
    a. Where feasible, authorized, or approved, on-board testing would be the preferred method. Many Alaska cruise ship destination communities have very little laboratory capacity, which often requires specimens to be transported to shore, and then further shipped to the Alaska State Public Health Laboratories or to commercial laboratories in the Lower-48 states. This adds an additional layer of time necessary for resulting, which may not be effective for diagnostic testing. Continuous screening testing may be conducted in this manner, and should be arranged directly between operators and commercial diagnostic laboratories.

b. How frequently should cruise ship operators test all passengers and crew?
    a. We recommend all passengers get tested within 72 hours of departure to the port of embarkation, followed by an additional test 7 to 14 days after embarkation. In addition, any passenger who displays signs or symptoms of COVID-19, regardless of severity, should undergo additional testing. If on-board collection, processing, and resulting can be accomplished, symptomatic passengers and anyone sharing a cabin should quarantine in their cabin to the maximum extent practicable until results are provided.

    Crewmembers should be subject to continuous screening testing (in addition to immediate diagnostic testing when symptomatic). The periodicity of screening testing should be no less than 100% of crewmembers once every 28 days. During initial sailing 100% of the crew should be tested at day 5 and day 8. If strict quarantine and entry testing is performed on new crew arrival, they should continue to be tested with the general crew population at least once every 28 days. For crewmembers who have contact with shore-based workers or local community members during port calls, 100% of those workers should be tested 7-10 days after on-shore contacts. If a vessel is in a maintenance window, and crew remains aboard for more than 21 days with no contact between crew and passengers, no continuous screening testing should be required.

c. What would be the anticipated financial cost of testing all passengers and crew?
    a. No Comment

5. Because reports of illness may lead to restrictions on crew activities, how should cruise ship operators encourage crew members to report mild symptoms of COVID-like illness to medical personnel?
    a. Operators should designate adequate isolation or quarantine quarters aboard the vessel that prioritizes minimal exposure while allowing for some freedom of movement for crewmembers to be able to leave the quarters but remain in the isolation or quarantine area for periods of time, as opposed to requiring ill crewmembers to be confined to

small crew-quarters for the entire quarantine or isolation period. When possible, operators should ensure sufficient quarters and areas of the ship are available for multiple persons under monitoring or investigation, and not plan to disembark ill crew to shoreside facilities unless the on-board medical provider deems it necessary to transfer the patient to a higher level of care.

a. How should cruise ship operators encourage medical personnel to report these cases to CDC?
    a. They should report cases to the Anchorage CDC Quarantine Station, USCG, and Alaska Division of Public Health in accordance with the *Alaska Multi-Agency Maritime Communicable Disease Emergency Response Plan*.

6. What should be the medical capacity to manage an outbreak or a severe case of COVID-19 on board the ship?
    a. The specific capacity should be recommended based on overall crew and passenger capacity, configured for COVID-19 capacity restrictions, as opposed to an arbitrary percentage or number of cases/patients. It will be important to consider the capacity to quarantine close contacts of COVID-positive cases as well. Most ports of call in Alaska have very limited healthcare and medical infrastructure, and operators should take steps to keep passengers and crew aboard for all but the most severe cases requiring a higher level of care, as diagnosed by on-board medical providers.

a. What arrangements should cruise ship operators have with private companies to transport and obtain medical care shoreside for passengers and crew with severe COVID-19?
    a. Operators should have robust plans and pre-arranged contracts in place with aeromedical and ground transport companies in the region to which they sail, or in specific Alaskan communities. As noted previously, Alaska's healthcare and medical capacity is very limited in most ports of call, and should be prioritized for the care of Alaska residents when possible. Those arrangements should include transport to specific locations in the Lower-48 states where additional arrangements have been made with local healthcare providers to accommodate COVID-positive care of patients.

7. What pre-arrangements should be made to ensure that all U.S. seaport communities will accept a returning ship after a COVID-19 outbreak is identified?
    a. Operators have worked hand-in-hand with Alaska seaport communities to ensure response planning has been conducted and agreed upon. Due to the limited infrastructure in most Alaska seaport communities, it may be advisable for operators to sail to Lower-48 seaports for significant outbreaks. CDC should encourage consistency in seaport communities' requirements and restrictions to the maximum extent possible.

8. What plans should cruise ship operators have for operationalizing shoreside quarantine facilities in the event of a COVID-19 outbreak on board a ship, without exposing the public and without relying on Federal, State, or local resources?
    a. Where practicable, operators should enter into pre-arranged contracts with commercial lodging, transportation, and feeding companies to support shoreside quarantine. Due to the limited lodging, dining, and healthcare infrastructure in Alaska, facilities may need to be identified outside of the port of call, and potentially in the Lower-48 states.

9. Due to obstacles with commercial travel thus far, what pre-arrangements should cruise ship operators make with the airline industry to accept crew and passengers from ships not affected by COVID-19?
    a. For crew and passengers from ships not affected by COVID-19, operators should ensure that clear and consistent airline or State of Alaska requirements are provided from the very beginning, either at the time of booking or at the employee on-boarding process. Universal masking, social distancing and hygiene protocols should all be provided to crew and passengers. Suggestions for pre-travel quarantine should be provided as well.

10. How should cruise ship operators address specific country travel restrictions that emerge as COVID-19 activity increases in geographical areas, such as

a. border closures preventing passengers and crew from repatriating?

a. Operators should develop robust outbreak response plans that include contracted air travel from Alaska seaport communities to Lower-48 communities where practicable.

b. seaport closures preventing porting of ships?

a. No Comment

c. embarking passengers originating from countries with heightened COVID-19 activity?

a. Passengers originating from countries with heightened COVID-19 activity should follow the requirements and restrictions put in place by CDC and the U.S. Department of Homeland Security for entry into the United States.

11. What measures should cruise ship operators be required to take to reduce the burden on U.S. government resources if foreign seaports deny cruise ships the ability to come into port during a voyage?

a. Operators should have detailed contingency plans that include options to return to the port of embarkation or alternate U.S. seaports should foreign seaports deny cruise ships the ability to make foreign port calls.

12. Given difficulties cruise ship operators have experienced when repatriating crew via non-commercial transportation, what preparations should the industry make to repatriate passengers or crew via non-commercial transportation after COVID-19 is identified on board?

a. No Comment

13. What innovations should cruise ship operators develop to reduce transmission of COVID-19 on board ships and how would these innovations be effective?

a. Congregate dining, recreation, and entertainment facilities should be reconfigured to maximize the opportunity for social distancing of passengers and crew, allowing family or small cohort groups of passengers or crew to be together. Shipboard activity and work schedules should be modified/staggered to reduce the overall number of participants at any one activity. Robust pre-boarding quarantine, screening, and testing should be recommended. Physical distancing or barriers should be considered in areas of the vessel where it makes sense (casinos, theatres, dining rooms, etc.). Onboard bars and entertainment venues should explore the ability to physically separate entertainers (in particular bands and singers) from other crewmember and passengers.

14. Should cruise ship operators implement other interventions to decrease or prevent the spread of COVID-19 on board ships?

a. Operators should explore the feasibility of retrofitting onboard ventilation systems. Minimizing the amount of crew changeover should be considered, and shore leave policies adjusted to minimize potential exposure of the workforce.

15. What evidence of efficacy or other rationale exists for any public health interventions that cruise ship operators propose to take on board ships?

a. No Comment

Resumption of Passenger Operations

16. What steps should cruise ship operators take to prevent the introduction of COVID-19 onto ships after resuming passenger operations?

a. Answered above.

a. Should cruise ship operators deny boarding to passengers with COVID-like illness or confirmed infection with COVID-19?

a. Yes. Early identification through the use of pre-travel and pre-boarding testing and screening should be utilized to identify those passengers as early as possible.

b. Should cruise ship operators deny boarding to passengers with known exposure to a person with COVID-19 during the previous 14 days?

a. Yes. Known exposure or close contacts should continue to follow quarantine and/or quarantine and testing requirements that may be in place at the time of sailing.

c. What methods should cruise ship operators use to screen for exposures and detect COVID-like illness in passengers seeking to board the ship?

a. Multiple proactive screenings though affirmative health questionnaires, and temperature screening, should be conducted during the arrival, terminal, and boarding process. FDA and CDC approved testing should be required prior to embarkation of all passengers.

d. Should cruise ship operators deny boarding to passengers coming from COVID-19 high-incidence geographic areas?

a. Passengers coming from COVID-19 high-incidence geographic areas should follow federal recommendations of CDC and the U.S. Department of Homeland Security prior to arrival at the port of embarkation. It would be impractical for operators to conduct travel or point of origination investigations on all passengers.

e. How should cruise ship operators manage embarking crew with COVID-like illness, known exposure, or coming from high-incidence geographic areas after resuming passenger operations?

a. Operators should consider developing crew travel and quarantine procedures and infrastructure to support onshore quarantine of crewmembers with COVID-like illness or known exposure, until crewmembers are medically released from isolation or quarantine. Alaska has detailed examples of pre-arrival testing and quarantine requirements for fishing industry employers at https://covid19.alaska.gov/health-mandates/.

f. Should cruise ship operators test passengers and crew pre-boarding? If yes, what should the testing protocol be?

a. Yes. Operators should consider pre-arrival testing within 72 hours of departure to the port of embarkation, with and additional test between 7-14 days of embarkation.

g. Should cruise ship operators transport and house passengers and crew denied boarding at the seaport to avoid exposing the public?

a. Yes.

17. Should cruise ship operators plan to reduce passenger and crew loads to decrease the risk of transmission on board the ship?

a. Yes. Capacity reductions should be considered in order to maximize social distancing opportunities and to accommodate activity scheduling to minimize close contacts to the maximum extent practicable.

a. To what extent and for how long should cruise ship operators reduce passenger capacity?

a. No Comment

b. To what extent might reducing passenger capacity affect the economic viability of cruise lines?

a. No Comment

c. Should cruise ship operators be required to provide scientific evidence that reducing passenger capacity will prevent transmission on board?

a. No Comment

18. Should cruise ship operators decrease the length of voyages and, if so, by how much?

a. No. If extended-length voyages occur, we recommend that operators should consider additional mid-voyage testing of passengers along with the continuous screening testing of crew discussed above.

a. How would decreasing the length of voyages affect the transmission of COVID-19 on board the ship and in U.S. communities?

a. No Comment

b. Should cruise ship operators be required to provide scientific evidence that reducing length of voyages would decrease the risk of further introduction of COVID-19 to U.S. communities?

a. No Comment

19. Should cruise ship operators limit shore excursions?

a. Operators and shore side excursion vendors should consider limiting the amount of family groups or travel cohort groups as necessary to minimize large gatherings and congregate activities to the extent practicable and economically feasible.

a. What precautions should cruise ship operators take during shore excursions to prevent passengers and crew from being exposed to COVID-19?

a. In combination with the answer above, operators should require universal masking of passengers and comply with all local mandates and restrictions adopted to mitigate the introduction and transmission of COVID-19.

b. During shore excursions, how should cruise ship operators prevent transmission of COVID-19 into land-based communities?

a. See above. In addition, operators and shore side excursion vendors should consider limiting the opportunities for unstructured “free-time” for passengers and crews to travel throughout the community.

20. Should cruise ship operators restrict the number of persons per room (*e.g.,* maximum capacity of 2 adults per cabin)?

a. Cabin occupancy doesn’t necessarily need to be restricted, but operators should consider family group or small travel cohort group activities to the maximum extent practicable, to encourage passengers to interact within their family unit or small travel cohort.

a. Should cruise ship operators be required to provide single-occupancy rooms with private bathrooms for crew after resuming passenger operations?

a. Operators should consider reserving an appropriate number of single-occupancy rooms with private bathrooms for quarantine and isolation purposes.

21. What mental health services should cruise ship operators provide to crew and passengers during quarantine or isolation?

a. Robust onboard services should be made available to crew and passengers. Operators should consider quarantine and isolation areas onboard to allow limited, no-contact activity for those requiring quarantine or isolation.

22. What precautions should the cruise line industry take to safely disembark passengers and crew without transmitting COVID-19 into local seaport communities?

a. In addition to pre-travel and pre-embarkation health screening and testing, daily health screening (to include temperature checks) and pre-disembarkation screening of passengers and crew should be considered.

23. Should the cruise line industry immediately cancel cruise voyages if COVID-19 cases are identified on board or after disembarkation?

a. Not necessarily. Operators should have a robust case response plan in place that includes contact tracing, quarantine and isolation of cases and close contacts. Response plans should consider increased testing of passengers and crew upon case identification. In addition, operators should comply with the requirements of the *Alaska Multi-Agency Maritime Communicable Disease Emergency Response Plan* and comply with any orders or direction provided by state and local public health authorities, the CDC Anchorage Quarantine Station, and the USCG.

24. Because of the economic costs associated with cruising, some cruise ship passengers may be reluctant to cancel travel plans if they become ill or are exposed to COVID-19 or may try to hide symptoms of illness. Should cruise ship operators fully refund or provide incentives to passengers that:

a. Are denied boarding due to COVID-like illness symptoms, confirmed infection, or known exposure?

a. Yes. This should include the suggestion that passengers obtain travel and medevac insurance prior to their voyage.

b. are denied boarding due to coming from high-incidence geographic areas?

a. Yes. This should include the suggestion that passengers obtain travel and medevac insurance prior to their voyage.

c. request last-minute cancellations due to COVID-19 concerns?

a. Yes. This should include the suggestion that passengers obtain travel and medevac insurance prior to their voyage.

25. Due to the costs associated with seeking medical care on board, and the likelihood that sick passengers will be isolated and their travel companions quarantined for the remainder of their voyage, how should cruise ship operators encourage passengers to notify the medical center when they experience COVID-19 symptoms?

a. Up-front and clear communications on passenger expectations should be provided on operator and booking websites, and sent and acknowledged as part of the booking process. Daily health screening should be utilized in conjunction with continued communications and signage asking passengers to self-identify.

26. How should cruise ship operators decrease or eliminate the risk for COVID-19 transmission for both passengers and crew in the following group settings?

a. Embarkation and disembarkation?

a. Staggered schedules and timing, clearly marked social distancing signage, and hand sanitization should be used throughout all portions of the voyage. Universal masking should be required.

b. Safety drills and trainings?

a. Staggered schedules and timing, clearly marked social distancing signage, and hand sanitization should be used throughout all portions of the voyage. Universal masking should be required.

c. Dining?

a. Staggered schedules and timing, clearly marked social distancing signage, and hand sanitization should be used throughout all portions of the voyage. Universal masking should be required. Buffet-style options should be limited, and in-room dining options should be expanded.

d. Onboard entertainment events?

a. Staggered schedules and timing, clearly marked social distancing signage, and hand sanitization should be used throughout all portions of the voyage. Universal masking should be required. Operators should consider additional separation of entertainers who project their voice, and venue capacity restrictions should be considered.

d. Shore excursions?

a. Staggered schedules and timing, clearly marked social distancing signage, and hand sanitization should be used throughout all portions of the voyage. Universal masking should be required. See above for additional suggestions for shore excursions.

Summary Questions

27. What benefits can be expected in terms of averted deaths and illnesses and how does this compare to the expected financial costs of the above measures?

a. No Comment

28. Should cruise ship operators be required to designate a responsible company official who will accept legal responsibility for failure to implement measures to protect public health?

b. Company officials and vessel masters in general should be responsible for compliance with federal, state, and local requirements and/or restrictions. However, companies should clearly identify a COVID-19 safety official, and vessels should clearly designate an individual onboard for purposes of implementation of mitigation measures.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail

campaign. CDC will carefully consider all comments submitted to this docket. CDC does not accept public comment by email.

FLORIDA PORTS COUNCIL

JAXPORT

Port Canaveral

Port Everglades

Port of Fernandina

Port of Fort Pierce

Port of Key West

PortMiami

Port Manatee

Port of Palm Beach

Port of Panama City

Port of Pensacola

Port of Port St. Joe

Port St. Pete

Port Tampa Bay

September 21, 2020

Maritime Unit
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road NE, MS V18-2
Atlanta, GA 30329

RE: Docket No. CDC-2020-0087

The Florida Ports Council (FPC) serves as the professional association for Florida's 14 deepwater public seaports and their management. Seaports are one of the state's greatest economic assets, positively affecting every region and every resident. Whether moving over a hundred million tons of cargo annually or millions of cruise passengers, Florida's seaports generate and support a vast array of commerce. These seaports are the gateway for shipment of goods into and out of Florida and link our state to vital international markets. Prior to this pandemic, our seaports had a $117.6 billion economic impact on the state and account for more than 900,000 direct and indirect jobs.

We appreciate the measured response by the CDC and others to help this nation react to the impact of COVID-19 on our citizens and economy. Through a myriad of federal, state and local efforts every business activity but cruise passenger operations have restarted their operations under new guidelines to ensure the safety of the public and workers. Cruise passenger operations remain the only industry that has not been permitted to operate under any guidelines issued by federal health or safety officials.

The cruise industry makes an enormous contribution to the state of Florida and is one of the state's largest employers. The industry contributes over $8.5 billion to Florida's economy. Florida seaports account for close to two-thirds of all U.S. cruise embarkations and is the home to the top three cruise ports in the world. Carnival Corporation, Norwegian Cruise Line Holdings and Royal Caribbean Cruises, Ltd., which combined control more than three-fourths of the North American cruise industry's capacity, have their headquarters in Miami, as do other cruise lines. The purchases and other financial aspects of the cruise industry on Florida affect virtually every industry in the country and the state. These activities support over 154,000 jobs in Florida alone, and a total personal income impact on this state of $7.7 billion dollars.

The impact of this passenger industry is also felt throughout this nation and hemisphere. Cargo and other consumer activity transiting Florida's seaports to the Caribbean and other parts of Latin America also support tourism activity generated by the cruise industry during ports of. The inability of the cruise industry to commence operations continues to have a detrimental impact in

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Florida and beyond. In Florida alone, we estimate that economic activity losses will exceed $22 billion through 2020. If the cruise industry is still unable to operate into 2021, these economic losses will continue to mount for Florida and this nation.

We appreciate the efforts of the CDC to collect information to help ensure the safe resumption of passenger operations at Florida's seaports. In response to your request for information, we offer the following responses to questions relevant to Florida's seaports.

> Question 6a – what arrangements should cruise ship operators have with private companies to transport and obtain medical care shoreside for passengers and crew with several COVID-19?

Answer – Currently all severe medical emergencies are handled by cruise ship operators using available transportation services for severe cases of confirmed COVID-19. We recommend that this activity by the cruise ship operators continue as currently provided.

> Question 7 – what pre-arrangements should be made to ensure that all U.S. seaport communities will accept a returning ship after a COVID-19 outbreak is identified?

Answer -- The Florida Department of Health and the CDC currently have cooperative state/federal procedures to deal with existing COVID-19 cases in Florida. Prior to the federal order to cease all cruise activities at Florida seaports, the agencies worked with a layered command and control organization of cruise lines, local health agencies, healthcare providers, federal agencies (i.e. U.S. Customs and Border Protection and the U.S. Coast Guard) and port authorities to safely remove non-infected passengers and infected passengers from impacted cruise vessels.

Based on this experience, we recommend that the CDC in partnership with the Florida Department of Health develop a set of guidelines and protocols for the transportation and medical treatment for any people onboard a returning ship after a COVID-19 outbreak is identified. Guidelines should include procedures for testing prior to disembarkation, location and duration of any necessary isolation or quarantine, medical testing and surveillance procedures, and procedures for ending isolation or quarantine. Once these guidelines have been established, cruise ship operators and local communities can then develop necessary solutions to implement appropriate procedures.

> Question 8 – what plans should cruise ship operators have for operationalizing shoreside quarantine facilities in the event of a COVID-19 outbreak on board a ship, without exposing the public and without relying on Federal, State, or local resources?

Answer – Operational plans developed by cruise ship vessels for future voyages should identify adequate shoreside quarantine facilities, including quarantine and transportation services that could be used to isolate and quarantine affected passengers and crew. We recommend that cruise ship operators collaborate with local port authorities to make necessary arrangement prior to the start of any voyage.

Question 16a – should cruise ship operators deny boarding to passengers with COVID-line illness or confirmed infection with COVID-19?

Answer – Passengers with possible, probable, or confirmed COVID-19 illness should be denied boarding. Cruise lines should develop pre-boarding protocols to efficiently assure that passengers of concern are segregated for further examination, and if needed, safely removed from the terminal facility, limiting exposure to others.

Question 16b – should cruise ship operators deny boarding to passengers with known exposure to a person with COVID-19 during the previous 14 days?

Answer – Passengers with possible, probable, or confirmed COVID-19 illness and close contact with a person with COVID-19 during the past 14 days should be denied boarding.

Question 16c – what methods should cruise ship operators use to screen for exposures and detect COVID-like illness in passengers seeking to board the ship?

Answer – the U.S. maritime industry (including the cruise industry) and federal, state and local first responders currently use a layered approach for a variety of security and health procedures at our nation's seaports. We recommend a similar layered approach for medical screening at our nation's seaports. This layered approach could include requirements for a diagnostic test within 72 hours prior to embarkation or a rapid test prior to boarding the ship, the completion of a health screening questionnaire prior to travel (and submitted to the cruise line for approval), and multiple symptom tests prior to boarding public transportation and prior to transiting a cruise terminal. Cruise lines have experience in pre-boarding protocols for security and business reasons and could integrate additional health protocols into a pre-boarding process.

Question 16d – should cruise ship operators deny boarding to passengers coming from COVID-19 high-incidence geographic areas?

Answer – Passengers traveling from such geographic areas in the U.S. should be allowed to board the vessel so long as they present proof of a negative diagnostic

test within 72 hours of embarkation and successfully complete other required screening. If a travel ban is in effect from a geographic area outside of the U.S., those passengers should be screened at air or land ports of entry well in advance of arriving at the cruise terminal or vessel.

> Question 16e – how should cruise ship operators manage embarking crew with COVID-like illness, known exposure, or coming from high-incidence geographic areas after resuming passenger operations?

Answer – Cruise ship operators should deny boarding for any crew members with possible, probable, or confirmed COVID-like illness, or close contact with any know exposure within the past 14 days. However, crew members with a negative diagnostic test within 72 hours of embarkation should be permitted to board provided such crew members quarantine for at least 14 days in isolated rooms onboard the vessel. Crew members should be subject to routine medical screening to mitigate the risk of transmission.

> Question 16f – should cruise ship operators test passengers and crew pre-board. If yes, what should the testing protocol be?

Answer – similar to the answers for questions 16c and 16d, cruise ship operators should adopt a layered approach to medical screening. This can include proof of a negative diagnostic test at least 72 hours prior to embarkation or the requirement to complete a rapid test prior to boarding the ship.

> Question 16g – should cruise ship operators transport and house passengers and crew denied boarding at the seaport to avoid exposing the public?

Answer – Cruise ship operations should not be required to arrange for private transportation and accommodation for any passenger denied transit through cruise terminals or boarding the vessel. With respect to similar passenger activities at airlines or passenger rail travel, those industries are not held responsible for subsequent housing or transportation of passengers denied travel because of COVID-19 illness. We recommend a similar standard for the cruise industry, individual travelers that are denied embarkation due to COVID-19 illness should follow CDC and state requirements for quarantine and travel.

Cruise ship operators should utilize designated quarantine facilities ashore or identified travel services for crew denied boarding at the seaport.

> Question 22 – what precautions should the cruise industry take to safely disembark passengers and crew without transmitting COVID-19 into local seaport communities?

Answer – the guidelines suggested under question 7 should include protocols to notify the seaport and other federal, state and local officials if there is a COVID-19 confirmed or probable case onboard the vessel. As also suggested in the answer to question 7, those guidelines should include procedures for testing prior to disembarkation, location and duration of any necessary isolation or quarantine, medical testing and surveillance procedures, and procedures for ending isolation or quarantine. Once these guidelines have been established, cruise ship operators and local communities can then develop necessary solutions to implement appropriate procedures.

> Question 26a – how should cruise ship operators decrease or eliminate the risk for COVID-19 transmission for both passengers and crew during embarkation and disembarkation?

Answer – Similar to the guidelines suggested for questions 7 and 22, guidelines should be developed by the Florida Department of Health and the CDC to maintain clean cruise terminal facilities and maintain social distancing. Guidelines should include appropriate cleaning and sanitizing procedures, and embarkation and disembarkation procedures to ensure appropriate social distancing and transmission mitigation policies. Once these guidelines have been established, cruise ship operators and others can develop necessary solution to implement appropriate procedures.

Florida cruise terminal operators proactively initiated cleaning protocols directed at mitigating COVID-19 transmission in these terminals as cruise operations were shut down earlier in the year. These protocols can be adjusted as needed based on any updated required procedures, in coordination with government and industry partners.

Thank you for your consideration of the Florida Ports Council's responses to this request for information. We look forward to working with the CDC and the Florida Department of Health to help ensure the safe resumption of passenger operations at Florida's seaports.

Sincerely,

Doug Wheeler,
President & CEO

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502 East Jefferson Street, Tallahassee, Florida 32301 | **www. flaports.org**

PORT TAMPA BAY™

September 18, 2020

Maritime Unit
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS V18–2
Atlanta, GA 30329

Re: Docket No. CDC–2020–0087

The Tampa Port Authority (dba Port Tampa Bay) is Florida's largest port, handling over 37 million tons of cargo per year and encompassing over 5,000 acres. One of Port Tampa Bay's major strengths is the diversity of business handled. The port handles a wide variety of cargoes including liquid bulk, dry bulk, break-bulk, and containers, and is a major shipbuilding/repair center. Cruise ship activities are also a very important line of business for the port.

With a population in excess of 8 million people and welcoming over 60 million tourists/visitors per year, the Tampa Bay/Orlando I-4 Corridor region is a huge local market and the fastest growing region of the state, as well as a major driver behind Florida overtaking New York as the 3rd largest state by population. Cruise activity at Port Tampa Bay has surpassed 1 million passengers the past two years and provided significant economic impact to the Tampa Bay region.

Prior to the pandemic, the cruise industry contributed nearly $8.5 billion in direct spending to Florida's economy on an annual basis and supported more than 154,000 Florida jobs, representing $7.7 billion in total wages and salaries.

Port Tampa Bay appreciates the opportunity to provide comments to Docket No. CDC-2020-0087 regarding cruise ship planning and infrastructure and resumption of passenger operations. The cruise industry is a key part of the port's business portfolio, and we support the CDC's efforts to consider appropriate public health measures and ensure the safety of the cruise industry.

In response to the questions posed in the July 21, 2020 request for information, we offer the following responses to questions relevant to our port.

> Question 7. What pre-arrangements should be made to ensure that all U.S. seaport communities will accept a returning ship after a COVID-19 outbreak is identified?

In a collaborative effort with stakeholders including but not limited to cruise lines, local health agencies, healthcare providers, federal agencies (i.e. Unites States Customs and Border Protection, The United States Coast Guard) and port authorities, develop a comprehensive plan to accept a ship that has been determined to have COVID-19 outbreak that includes safe handling and transportation of (infected or affected) cruise guests and crew to designated place of treatment and/or quarantine.

Question 8. What plans should cruise ship operators have for operationalizing shoreside quarantine facilities in the event of a COVID-19 outbreak on board a ship, without exposing the public and without relying on Federal, State, or local resources?

Cruise lines should collaborate with the local port authority for alternative berthing options and to identify private facilities and private transport services that are available and appropriate for quarantine use.

Question 16. g. Should cruise ship operators transport and house passengers and crew denied boarding at the seaport to avoid exposing the public?

Yes. Cruise ship operators should utilize designated quarantine space for crew and/or passengers denied boarding and prearrange private transportation services to transport people to a pre-determined local hotel or similar facility.

Question 22. What precautions should the cruise line industry take to safely disembark passengers and crew without transmitting COVID-19 into local seaport communities?

In conjunction with measures taken onboard cruise ships to mitigate risk of transmitting COVID-19, port terminal facilities should follow CDC safety protocol, as well as, adopt their own protocols for maintaining clean cruise terminal facilities and the recommended social distancing.

Question 26. How should cruise ship operators decrease or eliminate the risk for COVID-19 transmission for both passengers and crew in the following group settings?
a. Embarkation and disembarkation?

Cruise lines should collaborate with local port authorities to adopt protocols for maintaining clean cruise terminal facilities and maintain recommended social distancing.

Thank you for consideration of Port Tampa Bay's responses to this request for information. We stand ready to help the CDC however possible as it considers how to best respond to the COVID-19 pandemic.

Best Regards,

A. Paul Anderson
President and CEO

BROWARD COUNTY FLORIDA
PORT EVERGLADES DEPARTMENT – Chief Executive & Port Director's Office
1850 Eller Drive, Fort Lauderdale, Florida 33316
954-468-0140 FAX 954-523-8713

September 21, 2020

Maritime Unit
Centers for Disease Control and Prevention (CDC)
1600 Clifton Road NE, MS V18-2
Atlanta, GA 30329

RE: Docket No. CDC-2020-0087

Dear Director Redfield:

Thank you for providing the opportunity to submit comments on the Request for Information on the restarting of the multi-day cruise industry in the United States. As you may be aware, Broward County's Port Everglades is the third busiest cruise port in the world. Of the 13,000 direct regional jobs supported by businesses at Port Everglades, approximately 6,000 are directly related to the cruise industry. Another 84,254 residents are employed in the local hospitality and tourism industry. Those jobs have been severely affected by the onset of COVID-19.

In addition to the Port's role as an economic engine and job creator for Broward County, we are also keenly aware of our responsibility to the community and our neighbors to do all we can to guard against the spread of the virus. Port Everglades, along with our federal, state and local health and law enforcement partners, began planning for the potential onset of COVID-19 in January 2020, around the same time the first COVID-19 case was identified in the United States. Despite the suspension of multi-day cruises since March 14, 2020, Port Everglades has been working to safeguard our port, our passengers and our neighbors from the COVID-19 virus by enhancing sanitation protocols, implementing touchless procedures wherever possible, installing more hand sanitizing dispensers, enforcing facial coverings and social distancing, ensuring air handling ventilation is operating properly, and adopting the latest guidelines from the CDC and other health organizations worldwide. Most importantly, we are working with our cruise line partners to ensure that cruise passengers can safely visit Broward County to embark and debark their cruises while interacting with local residents.

We believe that cruising can resume safely in the United States and urge the CDC to act quickly to develop standard protocols and guidelines that can be used by our cruise line partners to submit and expeditiously receive approvals from the CDC to resume sailings from U.S. ports. Below are the answers that we believe address questions in the RFI (CDC-2020-0087) that apply to the resumption of cruising at Port Everglades.

Question 6: What should be the medical capacity to manage an outbreak or a severe case of COVID-19 on board the ship?

> Question 6a. What arrangements should cruise ship operators have with private companies to transport and obtain medical care shoreside for passengers and crew with severe COVID-19?
> Answer: Cruise ship operators should have standing agreements with private companies to provide transportation to shoreside medical facilities, including the availability of multiple facilities that may be needed to respond to an incident involving a large number of affected passengers and/or crew. The use of government resources should be limited to emergency situations that exceed the capabilities of private providers.

Question 7. What pre-arrangements should be made to ensure that all U.S. seaport communities will accept a returning ship after a COVID-19 outbreak is identified?
Answer: Cruise operators must have an emergency response, quarantine and repatriation plan in place that can be readily implemented by the cruise line in coordination with the local health agency and the seaport's multi-agency Unified Command or similar interagency working group consisting of government agencies and health officials working directly with the cruise line. Part of the plan should include pre-arranged agreements with local medical facilities, ambulance services, and if necessary, air evacuation providers, to transport, treat and quarantine affected passengers and/or crew, without placing a burden on local resources.

Question 8. What plans should cruise ship operators have for operationalizing shoreside quarantine facilities in the event of a COVID-19 outbreak on board a ship, without exposing the public and without relying on Federal, State, or local resources?
Answer: For symptomatic or COVID-positive passengers, cruise operators must implement their CDC-approved emergency response and approved quarantine plan in coordination with the local health agency and the seaport's multi-agency Unified Command or similar interagency working group consisting of government agencies and health officials working directly with the cruise line. Part of the plan should include pre-arranged agreements with local medical facilities and ambulance services to transport, treat and quarantine affected passengers and/or crew. Additionally, cruise operators should ensure that there is adequate space on board the cruise ship for quarantine facilities to isolate persons affected by a COVID-19 outbreak until the ship can return to port and access shoreside facilities.

Question 10: How should cruise ship operators address specific country travel restrictions that emerge as COVID-19 activity increases in geographical areas, such as:

> Question 10b. Seaport closures preventing porting of ships?
> Answer: Cruise lines should have pre-arranged emergency response, quarantine and repatriation plans with all homeports and planned ports of call, including pre-negotiated arrangements with appropriate local officials, consulates and medical facilities. Cruise lines should also identify alternate ports of call if a diversion is necessary, and make the necessary arrangement with local officials and foreign consulates.

Question: 16. What steps should cruise ship operators take to prevent the introduction of COVID-19 onto ships after resuming passenger operations?

> Question 16a. Should cruise ship operators deny boarding to passengers with COVID-like illness or confirmed infection with COVID-19?
> Answer: Passengers who have confirmed COVID-19 illness or are symptomatic should be denied boarding.

> Question 16b: Should cruise ship operators deny boarding to passengers with known exposure to a person with COVID-19 during the previous 14 days?
> Answer: Denial of boarding of any passenger that tests negative for COVID-19 should only be considered for those who have had close contact (as defined by CDC guidance) within the previous 14 days with a person with a confirmed positive COVID-19 test.

> Question 16c. What methods should cruise ship operators use to screen for exposures and detect COVID-like illness in passengers seeking to board the ship?
> Answer: Consistent with the Florida Ports Council protocol, operators should require screening of all passengers and crew for COVID-19 completed within 72 hours prior to embarkation using a medically approved testing methods temperature checks and screening questionnaires. Shore staff checking in passengers should be trained to identify symptoms and report potential illness to the cruise line's designated health supervisor.

Question 16d: Should cruise ship operators deny boarding to passengers coming from COVID-19 high-incidence geographic areas?
Answer: Cruise ship operators should apply the same criteria as is applied to international air transportation at the time of the ship sailing.

Question 16e. How should cruise ship operators manage embarking crew with COVID-like illness, known exposure, or coming from high-incidence geographic areas after resuming passenger operations?
Answer: Cruise ship operators should deny boarding for any crew members with possible, probable, or confirmed COVID-like illness, or close contact with any known exposure within the past 14 days. However, crew members with a negative diagnostic test within 72 hours of embarkation should be permitted to board. Crew members should be subject to routine medical screening to mitigate the risk of transmission while aboard the ship.

Question 16f. Should cruise ship operators test passengers and crew pre-boarding? If yes, what should the testing protocol be?
Answer: Consistent with the Florida Ports Council protocol, cruise passengers should be tested within 72 hours of embarkation using a medically approved testing method. New crew members should be tested before being allowed to board the ship. A new crew member must not embark until a negative test result.

Question 16g. Should cruise ship operators transport and house passengers and crew denied boarding at the seaport to avoid exposing the public?
Answer: Cruise operators should remain responsible for providing transportation and appropriate shore facilities/housing to crewmembers denied boarding. Cruise operators should also work with local authorities to develop protocols to address passengers denied boarding to minimize the risk of community spread.

Question 19. Should cruise ship operators limit shore excursions?

Question 19a. What precautions should cruise ship operators take during shore excursions to prevent passengers and crew from being exposed to COVID-19?
Answer: Operators should ensure use of pre-approved tour operators selected by the cruise operator that comply with an approved COVID plan and local protocols and ordinances, whichever is more stringent.

Question 19b. During shore excursions, how should cruise ship operators prevent transmission of COVID-19 into land-based communities?
Answer: Cruise operators should emphasize to passengers upon docking that they must use pre-approved, regularly screened vendors that adhere to the ship's sanitation, PPE and COVID-19 plan for excursions to ensure that there is minimized contact with anyone ashore who may have the COVID-19 virus.

Question 22. What precautions should the cruise line industry take to safely disembark passengers and crew without transmitting COVID-19 into local seaport communities?

Answer: As passengers and crew were tested upon embarkation and screened throughout the cruise, operators must continue their COVID-free passenger protocol on land during port-of-call visits using pre-approved tour operators. At homeports, where passengers are disembarking at the end of their cruise, passengers and crew must be screened before disembarkation, and any COVID-19 positive or symptomatic persons must be managed using the approved response plan.
All embarking/disembarking passengers and crew must be informed about the local community's COVID-19 prevention practices and restrictions, including local emergency orders and mandates.

Question 26. How should cruise ship operators decrease or eliminate the risk for COVID-19 transmission for both passengers and crew in the following group settings?

Question 26a. Embarkation and disembarkation?
Answer: Cruise ship operators' approved plans should prescribe that passengers and crew practice the CDC guidelines on social distancing, facial coverings, sanitizing, etc. Cruise ship protocols should require testing passengers using a medically approved testing method completed within 72 hours prior to embarkation and employ health screenings prior to disembarkation. In addition, each new crew member assigned to the ship must not embark until a negative test result is received and should be quarantined according to their CDC approved plan.
All disembarking passengers and crew must be informed about the local community's COVID-19 prevention practices and restrictions, including local emergency orders and mandates.

Thank you again for providing us with this opportunity to submit comments for your consideration.

Sincerely,

Jonathan T. Daniels
Chief Executive and Port Director

Cc: Glenn Wiltshire, Deputy Port Director
Bertha Henry, County Administrator
Andrew Meyers, County Attorney

EXHIBIT B

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

April 28, 2021

Dear Cruise Industry Colleagues,

Since April 12, 2021, senior leadership from the Centers for Disease Control and Prevention (CDC) and other relevant federal agencies have engaged in twice-weekly meetings with representatives from various cruise lines. The objective of these meetings has been to engage in dialogue and exchange information with individual cruise line representatives[1] regarding the impact of vaccines[2] and other scientific developments since the Framework for Conditional Sailing Order (CSO) was issued in October 2020. Participants had the opportunity to ask operational questions about the CSO and CDC's published technical instructions for cruise ships.

During these discussions, individual cruise line representatives were able to express their concerns as to the pace and phases of the CSO, ask questions related to the implementation of the CSO, and reiterate their desire to resume cruising as soon as possible. CDC subject matter experts discussed the public health challenges of cruising safely and responsibly during a global pandemic, particularly regarding the emergence of SARS-CoV-2 variants of concern. These challenges include ensuring cruise ship passenger operations are conducted in a way that protects crew, passengers, port personnel, and U.S. communities. CDC experts explained the rationale behind certain requirements of the CSO and similarities with other requirements and recommendations regarding maritime operations from international public health entities.

We acknowledge that cruising will never be a zero-risk activity and that the goal of the CSO's phased approach is to resume passenger operations in a way that mitigates the risk of COVID-19 transmission onboard cruise ships and across port communities. We remain committed to the resumption of passenger operations in the United States following the requirements in the CSO by mid-summer, which aligns with the goals announced by many major cruise lines. In furtherance of this mutual effort, we provide the following clarifications to its Phase 2A technical instructions issued on April 2, 2021.

We look forward to reviewing plans submitted by the cruise lines for Phase 2A and moving into the next phase of the CSO soon.

Clarifications

Timeline to resuming passenger operations under the phased approach

- The 30 calendar day timeframe for the submission to CDC of a cruise ship operator's notice for conducting a simulated voyage and the 60 calendar day timeframe for submission to CDC of the

[1] Cruise industry participants included American Queen Steamboat Company, Bahamas Paradise Cruise Line, Carnival Corporation, Cruise Line International Association, Disney Cruise Line, Norwegian Cruise Line Holdings, Royal Caribbean Group, and Viking Cruises.

[2] As part of these discussions, CDC reviewed CLIA's vaccine position statement which CDC understands to be that trade group's current position regarding the role of vaccines in restarting cruising.

cruise ship operator's COVID-19 Conditional Sailing Certificate application as set forth in the CSO are suggested as guidelines. CDC Maritime Unit will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

- CDC encourages the finalization of the Phase 2A port agreements to allow cruise ships to embark non-essential crew for simulated and restricted voyages. Prior to finalization of the Phase 2A agreements with port and local health authorities, CDC will allow cruise ships to embark 50 percent of the non-essential crew expected to sail on the first restricted voyage. CDC expects that a full complement of crew will not be needed for a cruise ship operator to conduct a simulated voyage because such simulations may be conducted with a small percentage of passengers.

Phase 2A: Port agreements – General Components

- In documenting the approval of all U.S. port and local health authorities where the ship intends to dock or make port during one or more 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. Such multi-port agreements may be particularly suitable if one port has limited medical or housing capacity and a nearby port is able to supplement these capacities.

Phase 2A: Port agreements – Vaccination Components

- In completing the vaccination component of a Phase 2A agreement, including a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, cruise ship operators must disclose and document their current plans to vaccinate crew. This includes if a cruise ship operator only plans to encourage crew to be vaccinated on a voluntary basis once vaccines become more widely available.
- In completing the vaccination component of a Phase 2A agreement, including presentation of proposals regarding how the cruise ship operator intends to incorporate vaccination strategies to protect passengers, cruise ship operators must disclose and document their current strategy. This includes if a cruise ship operator only plans to encourage passengers to be vaccinated on a voluntary basis once vaccines become more widely available.

Phase 2A: Port agreements – Medical and Housing Components

- In determining the sufficiency of shoreside medical and housing facilities, port authorities and local health departments should consider the cruise ship operator's plan and timeline for vaccination of crew and presentation of proposals incorporating vaccination strategies to maximally protect passengers. Those cruise ship operators with a clear and specific vaccination plan and timeline may have only a limited need for shoreside medical and housing facilities compared to operators who only plan or propose to encourage vaccinations.

Phase 2A: Port agreements – Medical Components

- CDC acknowledges that shoreside medical facilities and healthcare systems cannot guarantee bed capacity. In documenting a cruise ship operator's contractual arrangement with such

facilities or systems, redundant contracts, or contracts allowing for preferential acceptance of patients on a space-available basis, will be considered acceptable.

Phase 2A: Port agreements – Housing Components

- In determining whether a cruise ship operator has contractual arrangements for shoreside housing facilities in sufficient quantities to meet the needs of travelers for isolation or quarantine, the parties to a Phase 2A agreement may consider the ability of travelers to use their own personal vehicles to return safely to their residences. The parties should consider the time needed for travelers to drive to their final destinations to avoid the need for overnight stays en route. At a minimum, the health department at the final destination must be notified and travelers must be advised to complete their isolation or quarantine at home. For more information, please visit CDC's Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID-19 or COVID-19 Exposure webpage.
- CDC routinely works with state and local health departments and the U.S. Department of Homeland Security to prevent travelers from boarding commercial airplanes if they:
    - are known or suspected to have a contagious disease, or
    - were exposed to a contagious disease that poses a threat to the public's health.
        - For more information see Travel Restrictions to Prevent the Spread of Disease.

  Accordingly, the parties to a Phase 2A agreement should consider the housing needs of travelers who are unable to return to their residences by private vehicle as they will not be permitted to board commercial flights.

- In documenting that the parties to a Phase 2A agreement have deliberated and jointly considered the needs of travelers under quarantine or isolation, including needs relating to security and legal considerations to prevent travelers from violating any mandatory isolation or quarantine, it is assumed that a government entity may issue an order for mandatory isolation or quarantine, and that the cruise ship operator would cooperate with the government entity in addressing security needs.
- Referencing the requirement that shoreside housing provide separate ventilation systems for all travelers who are not part of the household, CDC notes that a standard hotel room with a thermostat on the wall or individual air handling unit is an example of housing that would meet this requirement.

We remain committed to providing any requested technical assistance with Phase 2A agreements and looks forward to receiving these port agreements from the industry. Any technical questions from the cruise ship operators or other relevant stakeholders regarding the Phase 2A port agreements should be addressed to eocevent349@cdc.gov.

We would like to take this opportunity to provide you with our current thinking regarding the following possible updates.

Upcoming Updates

Color-coding update

- Cruise ship operators may be allowed to use commercial travel to disembark crew regardless of the cruise ship's color status. Cruise ship operators will be restricted from using commercial travel for crew who have tested positive for SARS-COV-2, the virus that causes COVID-19 (unless they have documentation of recovery from a COVID-19 infection in the previous 90 days) and are within their isolation period and their close contacts (unless fully vaccinated) who are within their quarantine period.

Testing and quarantine updates during restricted voyages based on vaccination status

- CDC will update testing and quarantine requirements for passengers and crew to closely align with CDC's guidance for fully vaccinated and not fully vaccinated persons.

	Not Fully Vaccinated Crew	Fully Vaccinated Crew
Embarkation Day Testing	- NAAT	- Viral (NAAT or antigen)
Quarantine Testing [& Duration]	- NAAT [end quarantine after day 10 if negative]	- Viral (NAAT or antigen) [end quarantine after day 7 if negative]
End of Quarantine Testing	- NAAT	- Viral (NAAT or antigen)
Routine Screening Testing	- Viral (NAAT or antigen)	- Viral (NAAT or antigen)
Disembarkation Day Testing	- Viral (NAAT or antigen)	- Not applicable

Updates for fully vaccinated passengers and crew

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

We appreciate your support, and that of our partners, as we work together to fight COVID-19.

Sincerely,

CAPT Aimee Treffiletti, USPHS
Maritime Unit
Global Migration Task Force

CC:
Gary Rasicot
Department of Homeland Security

Joel Szabat
Department of Transportation

EXHIBIT C

Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC's Framework for Conditional Sailing Order

Audience

This document is intended to assist cruise ship operators in preparing to conduct simulated ("trial") voyages in advance of restricted passenger voyages under a COVID-19 Conditional Sailing Certificate. This includes conducting simulated voyages 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 as per the terms of CDC's Framework for Conditional Sailing Order (CSO), developing an after-action report, and addressing any identified deficiencies.

Purpose

This document provides technical instructions for Phase 2B of CDC's CSO for cruise ship operations in U.S. waters to ensure health and safety protections for travelers (crew and future passengers) and port personnel prior to resuming passenger operations in a way that mitigates the risk of spreading COVID-19.

These instructions are not intended as, and do not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

Notifying and Requesting CDC Approval to Conduct a Simulated Voyage

A cruise ship operator should notify CDC and request CDC's approval to conduct a simulated voyage at least 30 calendar days[1] prior to the date on which the cruise ship operator proposes to conduct the simulation. Submit notifications and requests to CDC electronically through eocevent349@cdc.gov. Additionally, this notice and request for approval must:

- Specify the dates and location of the proposed simulation.
- Verify that the cruise ship operator is eligible to conduct a simulated voyage as per the terms of the CSO and these technical instructions.

[1] The 30-calendar day timeframe is suggested as a guideline. CDC will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

- Submit documentation that the cruise ship operator has a written agreement (or a multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for Phase 2A of CDC's CSO.
- Provide a copy of the cruise ship operator's proposed written notification to volunteer passengers. This written notification must advise volunteer passengers that they are participating in health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers.
- Provide a copy of the cruise ship operator's proposed informed consent form to be signed by all persons who will be participating as volunteer passengers in the simulated voyage. This proposed informed consent must advise all such persons that the simulated voyage will be conducted on a consensual basis and not as a condition of employment or in exchange for consideration or future reward. For the purpose of these technical instructions, passage on board the ship, accommodations, provision of food and beverages, participation in shore excursions and private island visits, and attendance at entertainment events while participating as part of a simulated voyage will not be deemed a form of consideration. At the cruise ship operator's discretion, this written informed consent can be obtained either on paper or electronically using a digital signature.
- Identify and provide one or more points of contact for persons who will be overseeing and implementing the proposed simulation for each cruise ship. This must include points of contact who will be physically present on the ship during the simulated voyage.
- Include the protocols or practices to be simulated, which must, at a minimum, incorporate the requirements for conducting simulated voyages under these technical instructions.
- Be signed by the cruise ship operator's responsible officials, meaning 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.
- 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 (i.e., Phase 1 of the CSO) have been satisfied and continue to be met.

CDC will respond to these requests in a timely manner. CDC may deny the request to conduct a simulated voyage if the cruise ship operator is not in compliance with any of CDC's requirements for the mitigation of COVID-19 onboard cruise ships, technical instructions, or orders, or if in CDC's determination the simulated voyage does not provide adequate safeguards to minimize the risk of COVID-19 for all participants. CDC may also oversee and inspect any aspect of the simulated voyage, including through in-person or remote means allowing for visual observation.

Eligibility for Conducting a Simulated Voyage

As part of the cruise ship operator's notification and request to conduct a simulated voyage, a cruise ship operator must verify that it meets the following eligibility criteria:

- The cruise ship operator has 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.
- The cruise ship operator has continued to submit the Enhanced Data Collection (EDC) form as specified in CDC technical instructions or orders. If the cruise ship has been operating outside of U.S. waters, the cruise ship operator has submitted the EDC form during (at a minimum) the 28 days preceding the ship's expected arrival in U.S. waters and will continue to submit the EDC form after the ship enters U.S. waters.
- The cruise ship operator has observed and continues 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.
- The cruise ship operator has arranged for and submitted and continues to arrange for and submit laboratory test results as required by CDC for every crew member on board ships operating in U.S. waters. If the cruise ship operator has ships operating outside of U.S. waters and intends for these ships to return to operating in U.S. waters while the CSO remains in effect, then the operator has arranged for and submitted laboratory test results as required by CDC for every crew member on board these ships.
- If the cruise ship received any ship-to-ship transfers in the last 14 days, crew were only transferred from a cruise ship with no confirmed COVID-19 or COVID-like illness during the 14 days before the transfer occurred.
- If the cruise ship received any land-based embarking crew, such crew were laboratory tested for SARS-CoV-2 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.
- The cruise ship operator has a written agreement (or multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for Phase 2A of CDC's CSO. The written agreement must include a:
    - port component (including a vaccination component) between the cruise ship operator and port authority to determine the number of cruise ships operating out of 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;
    - medical care component between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and

- housing component between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and close contacts, identified from the day of embarkation through disembarkation for each voyage.

Requirements Relating to Volunteer Passengers

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard a cruise ship. This includes using volunteers simulating the role of passengers. A cruise ship operator must observe the following requirements relating to volunteer passengers:

- The minimum number of required volunteer passengers for each simulated voyage must be at least 10% of the maximum number of passengers permitted onboard for restricted voyages as per the terms of the cruise ship operator's Phase 2A agreement with U.S. port and local health authorities.
- The cruise ship operator must advise volunteer passengers of CDC's Travel Health Notice for COVID-19 and Cruise Ship Travel prior to the simulated voyage. At the cruise ship operators' discretion, this information can be provided via linking to CDC's webpage, through email, or written letter to the volunteer passengers.
- All volunteer passengers must be informed in writing that they are participating in a simulation of health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers. A copy of this written notification must also be provided to CDC as part of the cruise ship operator's notification and request to conduct a simulated voyage.
- All volunteer passengers must be at least eighteen years old or older on the day of the simulation and at the time that their consent to participate is obtained.
- The cruise ship operator must ensure **all** volunteer passengers have either:
  - Proof of being fully vaccinated against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO); or
  - If not fully vaccinated, written documentation from a healthcare provider or self-certified statement that the volunteer passenger has no medical conditions that would place the volunteer at high risk for severe COVID-19 as determined through CDC guidance.
- The simulation must be conducted with the signed informed consent of all participants and not as a condition of employment or in exchange for consideration or future reward. For the purpose of these technical instructions, passage on board the ship, accommodations, provision of food and beverages, participation in shore excursions and private island visits, and attendance at entertainment events while participating as part of a simulated voyage will not be deemed a form of consideration. The cruise ship operator must document this signed informed consent for each participant in writing, either on paper or electronically. The cruise ship

operator must also preserve the paper or electronic consent forms and make them available to CDC upon request at any time while the CSO remains in effect.

- All volunteer passengers must be evaluated for signs and symptoms of COVID-19 prior to embarkation and disembarkation. Cruise ship operators must educate all volunteer passengers about the signs and symptoms of COVID-19 and the need to notify cruise ship medical staff immediately if symptoms develop.
- All volunteer passengers must agree in writing to post-disembarkation specimen collection for COVID-19 testing at 3 to 5 days after completion of the simulated voyage. Cruise ship operators are advised that as a condition of receiving a COVID-19 Conditional Sailing Certificate, at least 75% of all volunteer passengers must provide their post disembarkation specimen to the selected laboratory (see options for post-disembarkation testing below) for COVID-19 testing within the specified time frame. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
- To facilitate contact tracing, the cruise ship operator must advise all volunteer passengers to notify the cruise ship operator if they develop symptoms of COVID-19 or are diagnosed with COVID-19 with any SARS-CoV-2 viral test within 14 days after the voyage. Passengers who develop symptoms within 14 days should be advised to be tested. The cruise ship operator must in turn report aggregate results to CDC in the after-action report.

Requirements Relating to the General Components of a Simulation and Simulated Activities

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 on board a cruise ship. This includes observing the general components of a simulation and simulating the following shipboard activities:

- At least one simulation must be conducted for each ship for which the cruise ship operator intends to commence restricted passenger voyages. The simulation(s) must occur prior to the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate under the CSO.
- The cruise ship's color-coding status must be Green or Orange at the time of the simulated voyage. If the cruise ship's color-coding status is Yellow or Red, then the simulation must be postponed until such time as the ship's status changes to Green or Orange. Cruise ship operators will not be required to submit a new request to conduct a simulated voyage in the event of postponement, but operators must notify CDC of the revised dates of the simulation.
- If the cruise ship operator has entered into a Phase 2A agreement with the port or local health authority of more than one port and the cruise ship operator intends for the ship to dock at more than one U.S. port during restricted passenger voyages, then the simulated voyage(s) must include each U.S. port.
- The cruise ship operator must maintain a list of all passengers, crew, port personnel, and other persons who participated in the simulated voyage. This list must be preserved and made available to CDC upon request at any time while the CSO remains in effect.

- Simulated voyages must be between 2-7 days in length with a least one overnight stay[2] to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard the cruise ship, including through embarkation, disembarkation, and post-disembarkation testing.
- Activities conducted on voyages that occurred outside of U.S. waters during the period of the No Sail Order (NSO) and the CSO that were not conducted as part of a CDC-approved simulated voyage, do not count towards the activities that must be simulated on a simulated voyage. However, cruise ship operators may incorporate best practices and lessons learned from these voyages as part of the simulation and in the after-action report submitted to CDC.
- The cruise ship operator must meet standards during the simulated voyage for hand hygiene, use of face masks, and social distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.
- The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.
- The following activities must be simulated onboard each ship for which the cruise ship operator intends to commence restricted passenger voyages before applying for a COVID-19 Conditional Sailing Certificate. However, at the cruise ship operator's discretion, these activities may be conducted as part of the same simulated voyage or as part of separate simulated voyages:
    - Embarkation and disembarkation procedures, as approved by U.S. port and local health authorities as part the cruise ship operator's Phase 2A agreements, including procedures for terminal check-in.
    - Onboard activities, including seating and meal service at dining and entertainment venues.
    - Medical evacuation procedures.
    - Transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms.
    - Onboard and shoreside isolation and quarantine, as per the terms of the cruise ship operator's Phase 2A agreements, of at least 5% of all passengers and non-essential crew.
    - Recreational activities that the cruise ship operator intends to offer as part of any restricted passenger voyages, e.g., casinos, spa services, fitness classes, gymnasiums.
    - Private-island shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on the private island:
        - Only one ship can port at the island at any one time.
        - A routine screening testing protocol must be implemented for island staff who are expected to interact with volunteer passengers or crew.
        - Mask use and social distancing must be observed on the island.
    - Port of call shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on port of call shore excursions:
        - Self-guided or independent exploration by passengers during port stops must be prohibited.
        - Shore excursions must only include passengers and crew from the same ship.

[2] To fully test all procedures during a simulated voyage, CDC recommends a minimum voyage length of 3 days with 2 overnight stays.

- Cruise ship operator must ensure all shore excursion tour companies facilitate social distancing, mask wearing, and other COVID-19 public health measures throughout the tour.
- Cruise ship operators must have a protocol for managing persons with COVID-19 and close contacts at all foreign ports of call. At a minimum, the protocol must include the following:
  - Disembarkation and housing of persons with suspected or confirmed COVID-19 needing shore-based hospital care and their travel companion(s) for the duration of their isolation or quarantine period.
  - Commercial repatriation of U.S.-based persons with COVID-19 and close contacts only after meeting criteria to end isolation and quarantine per CDC guidance. For commercial repatriation of foreign-based persons with COVID-19 and close contacts, cruise ship operators must consult with all relevant public health authorities.

Requirements Relating to Laboratory Testing

A cruise ship operator must observe the following requirements relating to laboratory testing of passengers and crew as part of a simulated voyage:

- Day of Embarkation Testing: The cruise ship operator must conduct laboratory testing of all passengers, without documentation of recovery from COVID-19 (as defined below), on the day of embarkation with same day results using one of the following testing instruments and processes:
  - Previously approved Phase 1 shoreside laboratory, or
  - Previously approved Phase 1 onboard point-of-care equipment, or
  - Other testing instruments and processes approved by CDC
    - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include “Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]” in the subject line as part of your request for CDC approval.
    - 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 specimens.
  - Results must be available prior to boarding the cruise ship. Volunteer passengers who test positive for SARS-CoV-2 should be denied boarding, unless determined to be a persistent positive by cruise ship medical personnel.
  - To be excluded from testing, passengers must show documentation of recovery from COVID-19 in the past 90 days, which includes the following:
    - Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
    - A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating

that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

- Day of Disembarkation Testing: The cruise ship operator must conduct laboratory testing of all passengers and any disembarking crew on the day of disembarkation with same day results using one of the following testing instruments and processes:
    - Previously approved Phase 1 shoreside laboratory, or
    - Previously approved Phase 1 onboard point-of-care equipment, or
    - Other testing instruments and processes approved by CDC
        - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include "Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]" in the subject line as part of your request for CDC approval.
        - 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 specimens.
    - Results must be available before the passenger leaves the cruise ship, seaport, or offsite testing location, but specimen collection and testing can occur onboard or shoreside.
- Post Disembarkation Testing Options: To validate the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard the cruise ship, post disembarkation testing for volunteer passengers is required for simulated voyages.
    - As a condition of receiving a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers provide their post disembarkation specimen to the selected laboratory for COVID-19 testing 3 to 5 days after completion of the simulated voyage for testing. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
    - The cruise ship operator must in turn report aggregate results to CDC in the after-action report.
    - Cruise ship operators have the option of supplying all volunteer passengers with a self-collected nasal mid-turbinate nucleic acid amplification test (NAAT) specimen collection kit to be shipped directly to a laboratory.
        - All volunteer passengers must:
            - Receive education on self-collection technique.
            - Be instructed to collect the specimen 3 to 5 days after completion of the simulated voyage for testing.
            - Be instructed to store and ship the specimen directly to the laboratory within the specifications of the manufacturer.
        - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the FDA reference panel for SARS-CoV-2 with a limit of detection (LOD) value ≤18,000 NDU/ml. CDC must approve the cruise ship operator's selection of a CLIA-certified

laboratory. All additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.

- Cruise ship operators can alternatively direct volunteer passengers to obtain a nasopharyngeal (NP) specimen at a shoreside laboratory for SARS-COV-2 testing 3 to 5 days after completion of the simulated voyage for testing.
  - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the FDA reference panel for SARS-CoV-2 with a limit of detection (LOD) value ≤18,000 NDU/ml. CDC must approve the cruise ship operator's selection of a CLIA-certified laboratory. All additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.

- Cruise ship operators must conduct laboratory testing of any passengers or crew who report illness consistent with COVID-19 during the simulated voyage (as well as any identified close contacts) using point-of-care equipment and parameters approved by CDC as part of Phase 1 of the CSO. Refer to the Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew for requirements of onboard COVID-19 testing for symptomatic travelers and close contacts.
- Cruise ship operators must continue to conduct routine screening testing of crew according to the corresponding color-coding interval. Cruise ship operators at their discretion may stagger whole ship crew testing during the corresponding color-coding interval (e.g., weekly, every two weeks, every 28 days). For example, the cruise ship operator may choose to test the same percentage of crew on each day of the week if required to test weekly. To ensure consistency, screening testing must be completed within 4 consecutive days of each color-coding interval and the testing schedule for each crew member should remain the same across all color-coding intervals.

Considerations Genetic Sequencing

If positive specimens are identified within 14 days after the voyage, it may be difficult to differentiate between exposures that occurred on board the ship and after disembarkation. In such situations the cruise ship operator may wish to request that a laboratory conduct genetic sequencing of SARS-CoV-2-positive specimens to determine the likelihood that the exposures occurred on board. If sequencing is being considered, please consult with CDC for additional information and instructions through eocevent349@cdc.gov. Results should also be made available to CDC as part of the after-action report. CDC will be available to assist cruise operators in interpreting results of any genetic sequencing.

- If sequencing will be performed: specimens can be stored at 2–8°C for no more than 72 hours from the time of collection. The 72-hour timeframe is a strict requirement for specimen quality. Specimens that require storage longer than 72 hours must be frozen at ≤ -70°C.
- If specimens are shipped: prior to shipping, specimens should be frozen at ≤ -70°C and shipped on dry ice. The quality of the specimen directly affects sequencing and virus culture success. Ideally, specimens should have a reverse transcription polymerase chain reaction (RT-PCR) cycle threshold (Ct) value of ≤28. If Ct values are not available, specimens that are positive/strong positive for SARS-CoV-2 may be sent (avoid weakly positive samples).

Advisory Related to Terminating a Simulated Voyage to Protect Health and Safety

CDC advises cruise ship operators that it may require them to immediately end a simulated voyage and take other actions to protect the health and safety of volunteer passengers and crew if a threshold of COVID-19 cases is met or exceeded during the simulation. During simulated voyages, this threshold is 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 for future simulated voyages or restricted passenger voyages based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors. In the event that 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 action-action report and how such deficiencies are to be corrected prior to approving any additional simulated voyages.

In addition, if a simulated voyage is ended early due to the above threshold being met or exceeded during the simulation, the cruise ship operator will have to repeat the simulated voyage at a later date. If the threshold for the voyage is met or exceeded during the simulation, the cruise ship operator will also have to advise all travelers to avoid commercial air travel or ground transportation for 14-days post voyage, unless they have one of the following:

- Proof of being fully vaccinated against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO), or
- Documentation of recovery from COVID-19 in the past 90 days, which includes the following:
    - Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
    - A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

Requirements Related to the Simulated Voyage After-Action Report (AAR)

A cruise ship operator must observe the following requirements relating to the post-simulation after-action report:

- The cruise ship operator must document in writing any deficiencies observed in its health and safety protocols and describe how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. A deficiency is any significant departure from the cruise ship operator's health and safety protocols or, if such health and safety protocols are followed, any documented transmission of COVID-19 that requires a

change, modification, or adjustment of the operator's protocols to ensure safer and healthier sailing.

- The cruise ship operator must report all post-disembarkation test results in aggregate to CDC in the after-action report. To obtain a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers provide their post disembarkation specimen to the selected laboratory for COVID-19 testing. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
- The after-action report must include the cruise ship operator's assessments and conclusions regarding the efficacy of its health and safety protocols at mitigating the risk of COVID-19 onboard a cruise ship and whether any changes, modifications, or adjustments to these protocols will occur based on "lessons learned" from the simulated voyage.
- Where appropriate, the cruise ship operator may incorporate into the after-action report discussion of best practices and lessons learned from voyages that occurred outside of U.S. waters during the period of the NSO or CSO and were not a part of the simulation.
- Where appropriate, the cruise ship operator may incorporate into the after-action report photographic, video, testimonial, or other evidence documenting that the simulated voyage was conducted in accordance with the cruise ship operator's health and safety protocols and these technical instructions.
- 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.
- 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. The findings and/or observations of these inspections will be shared with the cruise ship operator and must be incorporated into the operator's after-action report.

CDC will provide the cruise ship operator with a template for completing the after-action report after approving the operator's request to conduct a simulated voyage.

Role of Vaccinations During Simulated Voyages

- All participants who are fully vaccinated must follow all CDC Interim Public Health Recommendations for Fully Vaccinated People including recommendations related to wearing a well-fitted mask, maintaining physical distance (at least 6 feet), avoiding crowds, avoiding poorly ventilated spaces, covering coughs and sneezes, and washing hands frequently.
- For purposes of CDC guidance, cruise ships are considered residential, non-healthcare, congregate settings representing a global population.
- CDC may adjust testing parameters (e.g., types and specimen sources) and quarantine timeframes for all travelers based on increased vaccination coverage in the U.S. and globally, and advancements in testing options.

Option in Lieu of a Simulated Voyage

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

Simulated Voyages and the Passenger Vessel Safety Act

Cruise ship operators are advised that CDC has no responsibility for enforcing requirements relating to the Passenger Vessel Safety Act and no authority to waive these statutory requirements.

CDC's Mask Order

All persons, including port personnel, crew, and passengers (including those that are fully vaccinated) are advised that CDC's Order requires wearing of masks on conveyances entering, traveling within or leaving the United States, and in U.S. transportation hubs (see maritime-specific Frequently Asked Questions) remains in effect.

Reporting to Federal Agencies During Simulated Voyages

CDC requires daily submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form" for passengers and crew. This EDC Form will be used to conduct surveillance for COVID-19 on board cruise ships using cumulative reports of COVID-19-like illness, which includes acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) clinical criteria.

Access to the online EDC form has been provided to cruise lines by the Cruise Lines International Association (CLIA) or CDC. Cruise lines that do not have access should contact CLIA or CDC (email eocevent349@cdc.gov).

In addition to this daily surveillance via the online EDC form, cruise ship operators must continue to report to USCG via Advance Notice of Vessel Arrival (ANOA) as required by regulation. Cruise ship operators are reminded that USCG considers COVID-19 illness on board a cruise ship a hazardous condition and must be immediately reported to the local Captain of the Port when the cruise ship is within waters subject to the jurisdiction of the United States.

Acute Gastroenteritis (AGE) cases must be reported to CDC's Vessel Sanitation Program (VSP) in accordance with VSP's 2018 Operations Manual.

Illnesses of public health concern that are neither COVID-19 nor AGE, and all deaths must be reported to the CDC Quarantine Station with jurisdiction for the port.

COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order

Audience

This document is intended to assist cruise ship operators in ensuring health and safety protections during simulated and restricted passenger operations in a way that mitigates the risk of spreading COVID-19. This document is issued under CDC's Framework for Conditional Sailing Order (CSO) and its requirements must be observed in the same manner as other technical instructions issued under the CSO. This document also contains recommendations to further reduce the spread of SARS-CoV-2, the virus that causes COVID-19, that cruise ship operators should consider for incorporation into their health and safety protocols as best practices.

In addition, cruise ship operators must continue to adhere to requirements in CDC's Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew during passenger voyages.

CDC will update this information as needed and notify cruise ship operators of such updates.

Purpose

CDC's oversight and inspection of cruise ships during simulated and restricted passenger voyages will be based on this Operations Manual. The findings and/or observations of these inspections will be shared with the cruise ship operator. Cruise ship operators are expected to align their health and safety protocols with any CDC findings and observations. Such findings and observations must also be incorporated into the cruise ship operator's simulated voyage after-action report or as a condition of applying for and retaining permission to conduct restricted passenger voyages. Based on these inspections, CDC may also issue additional recommendations to the cruise ship operator that the operator should consider for adoption into their health and safety protocols as best practices.

As per the terms of the CSO, cruise ship operators, upon request, must make their properties and records available for inspection to allow CDC to ascertain compliance. 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.

Inspections of cruise ships during simulated and restricted passenger voyages:

- May be conducted by CDC with or without prior notification to the cruise ship operator;
- May be conducted by CDC through in-person or remote means;
- Will be conducted by CDC during a portion of the simulated voyage or restricted passenger voyage;
- May include CDC inspectors sailing on the simulated or restricted passenger voyage with prior notification to the cruise ship operator; and

- Will not have an associated fee[1] or inspection score.

Persons are prohibited from interfering with the ability of CDC inspectors to inspect and conduct oversight, 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.

This manual is not intended as, and does not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

Applicability of the VSP 2018 Operations Manual

Cruise ship operators must continue to follow the Vessel Sanitation Program (VSP) 2018 Operations Manual. In addition to ascertaining compliance in implementing and maintaining public health standards in accordance with the CSO's Technical Instructions, CDC inspectors will further evaluate adherence to environmental health and sanitation standards outlined in the current VSP 2018 Operations Manual.

All variances involving passenger interactive experiences previously approved by VSP are suspended until further notice.

CDC will recommend or direct the master of a vessel not to sail when an imminent health hazard is identified and cannot be immediately corrected, in accordance with VSP's 2018 Operations Manual.

Preventive Measures

Cruise ships involve the movement of large numbers of people in settings where they are likely to have close contact with one another. Close-contact environments facilitate transmission of SARS-CoV-2 and other respiratory viruses from person to person through exposure to respiratory droplets, aerosols, or contact with contaminated surfaces. Cruise ships may also be a means by which infected persons travel between geographic locations.

Requirements

To further reduce the spread of SARS-CoV-2, cruise ship operators must:

- Inform passengers of any mandatory public health measures prior to boarding
- Place posters in high-traffic areas that encourage hand hygiene to help stop the spread
- Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual

[1] When not under the Conditional Sailing Order, cruise ship operators pay a fee based on the ship's size for operational inspections or reinspections conducted by CDC's Vessel Sanitation Program. https://www.cdc.gov/nceh/vsp/desc/aboutvsp.htm

Cruise ship operators must continue to follow the preventative measures for crew outlined in CDC's Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Incorporate COVID-19 vaccination strategies to maximally protect passengers and crew in the maritime environment, seaports, and in land-based communities.
- Encourage passengers to avoid touching eyes, nose, and mouth with unwashed hands.
- Reduce face-to-face interactions between crew and passengers to the extent practicable.
- Discourage handshaking and encourage the use of non-contact methods of greeting.
- Promote respiratory and hand hygiene and cough etiquette.
- Inform passengers that use of cigarettes, e-cigarettes, pipes, or smokeless tobacco can lead to increased contact between potentially contaminated hands and their mouths.
- Place hand sanitizer (containing at least 60% alcohol) in multiple locations and in sufficient quantities to encourage hand hygiene

Surveillance for COVID-19

Because of the close-contact environment on cruise ships and the potential for asymptomatic and pre-symptomatic transmission, it is important that close contacts of individuals with SARS-CoV-2 infection be quickly identified and tested.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement procedures for maintaining records associated with active COVID-19 surveillance and make these records available to CDC upon request for review. These records include:
    - Surveillance log for acute respiratory illness (ARI), influenza-like Illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) symptoms, positive antigen results, and positive nucleic acid amplification test (NAAT) results.
    - Medical documentation of prior positive SARS-CoV-2 viral test results for crew.
        - Because retesting for SARS-CoV-2 is not recommended during the 90 days post lab-confirmed diagnosis (unless symptomatic), records must be available to review the ship's tracking of the 90-day timeframe for crew who have tested positive prior to these crew resuming routine laboratory testing.
    - Records relating to the isolation of persons positive for SARS-CoV-2 and the quarantine of close contacts. These include dates of isolation and quarantine, originally assigned cabin numbers, cabin numbers for isolation and quarantine, medical records, and sign and symptom logs.
    - Records relating to the contact tracing of any identified close contacts.
    - All medical records must be maintained for at least 90-days and must be made available to CDC upon request for review.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

- Consider the use of wearable recording technology, e.g. proximity bands, to rapidly identify close contacts if contact tracing is necessary.

Medical Centers

Medical centers on cruise ships can vary widely depending on ship size, itinerary, length of cruise, and passenger demographics.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Carry a sufficient quantity of personal protective equipment (PPE), medical and laboratory supplies listed on CDC's Interim Guidance for Ships on Managing Suspected or Confirmed Cases of Coronavirus Disease 2019.
- Healthcare personnel must adhere to Standard and Transmission-based Precautions when caring for patients with suspected or confirmed SARS-CoV-2 infection. Recommended PPE is described in the Infection Control Guidance.
- Maintain adequate supplies of antipyretics (e.g., acetaminophen and ibuprofen), antiviral and antimicrobial medications, oral and intravenous steroids, and supplemental oxygen. Information to estimate needed medical staffing and equipment can be found in the Federal Healthcare Resilience Task Force Alternate Care Site Toolkit, Supplement 2.
- As treatment and testing become more available in the United States, cruise ships must align with the latest CDC recommendations.
- Healthcare personnel must stay up to date on COVID-19 training and Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19).

Laboratory

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure that a CDC-approved onboard testing instrument is properly installed, and the CDC-approved assay is being used.
- Designate a laboratory point of contact (POC) responsible for managing quality assurance and quality control and decision-making.
- Ensure test results are traceable from specimen collection through reporting to the individual, including all supporting materials, records, and equipment.
- Follow assay storage and handling guidance found in the assay's FDA EUA Instructions for Use (IFU) document.
- Develop and maintain a **testing manual** to be followed on each applicable ship for the testing instrument and assay. The testing manual must be made available to CDC inspectors upon request for review.
    - The testing manual must include the following content:
        - CDC's Nasopharyngeal Specimen Collection Infographic

        - Specimen collection, storage, and handling procedures (NP swabs), including documentation and labeling of specimens
        - Instructions for Use (IFU) for the CDC-approved onboard testing instrument
        - Reporting procedures for results, including how results are reported and who receives test results
        - Equipment manual provided by the manufacturer
        - Procedure for daily documentation of testing location & reagent storage area temperatures
- Maintain the following records as part of the **testing manual** or in a separate document accessible to CDC inspectors:
    - Personnel training records for specimen collection, labeling, storage, testing, and reporting
    - Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed "Ready? Set? Test! Checklist" (regulatory sections do not apply)
    - Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed competency testing.
    - Documentation that all onboard medical personnel have read and reviewed:
        - Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing
        - "To Test or Not to Test? Considerations for Waived Testing"
        - "Ready? Set? Test! Patient Testing Is Important. Get the right results."
    - Preventative equipment maintenance records as specified by the manufacturer and quality assurance as described in the "Ready? Set? Test! Checklist"
    - Daily documentation of the testing & reagent storage area temperatures
    - Supplies/reagent inventory records (list of kits, reagents, supplies with lot numbers, expiration dates, storage conditions and other relevant information found in the IFU).
    - Documentation of corrective action if any quality assurance failures occur
    - Documentation of testing, including equipment logs, maintenance records, quality control documents, and test results
- Display instructions, infographics, and similar material in close vicinity to where the CDC-approved onboard testing instrument is used and in clear view of the medical personnel using the instrument. The following posters must be displayed near the onboard testing instrument:
    - Specimen collection instructions
    - "Ready Set? Test!" Poster

Infection Prevention and Control Plan

Infection prevention and control (IPC) is key to reducing the spread of SARS-CoV-2. Procedures and records associated with IPC implementation will be evaluated during inspections. Each cruise ship must maintain a written **Infection Prevention and Control Plan (IPCP)** that details standard procedures and policies to specifically address infection control and cleaning/disinfection procedures to reduce the spread of COVID-19.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must include the following as part of a written IPCP:

- Duties and responsibilities of each department and their staff for all passenger and crew public areas.
- Steps in IPC management and control and the triggers required for action at each step. At a minimum, triggers must address a graduated approach to IPC management in response to increasing case counts.
- Disinfectant products or systems used, including the surfaces or items the disinfectants will be applied to, concentrations, and required contact times. Use disinfectant products or systems that are listed on the Environmental Protection Agency (EPA) List N: Disinfectants for Coronavirus (COVID-19).
- Procedures for informing passengers and crew members that a threshold of COVID-19 has been met or exceeded. This section must address the procedures for notification of passengers and crew currently onboard the ship and those embarking the vessel on the subsequent voyage.
- Graduated procedures for returning the vessel to normal operating conditions after a threshold of COVID-19 has been met or exceeded, including de-escalation of cleaning and disinfection protocols.
- Procedures to protect passengers and crew from exposure to disinfectants, if not already included in the ship's safety management system. At a minimum, this must include the following:
    - Safety data sheets (SDSs)
    - PPE per CDC guidance for crew
    - Health and safety procedures to minimize respiratory and dermal exposures to both passengers and crew
- Procedures to align with the preventive measures based on the color-coding status outlined in CSO Technical Instructions.

Mask Use

At this time, all persons, including port personnel, crew, and passengers (including those that are fully vaccinated) are advised that CDC's Mask Order remains in effect and requires the wearing of masks on conveyances entering, traveling within or leaving the United States, and in U.S. transportation hubs (see Maritime-specific Frequently Asked Questions).

- While the Order permits temporarily removing a mask for brief periods of time while eating or drinking, removal of the mask for extended meal service or beverage consumption would constitute a violation of this Order.
- Masks do not have to be worn while inside one's own cabin

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Provide passengers and crew with information on how to properly wear, take off, and clean cloth masks.
- Remind passengers and crew not to touch their masks when wearing them.
- Position posters educating passengers on how to properly wear masks in high traffic areas throughout the ship
- Ensure bathers wear masks while congregating outside of recreational water facilities (RWFs) and while seated on the pool deck area. Masks do not need to be worn in the water, e.g., in RWFs or while swimming in the ocean. A wet cloth mask can make it difficult to breathe and likely will not work

correctly. This means it is particularly important for bathers to maintain social distancing of at least 6 feet (2 meters) when in the water with others who are not traveling companions or part of the same family.

Social Distancing

Strict adherence to passenger and crew testing protocols will aid in identifying potential cases of COVID-19 on board a cruise ship, however, continued prevention efforts are necessary to reduce the possibility of transmission to others if a case occurs on board the ship.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement social distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures in all congregate and high traffic areas of the vessel.
    - Dining (also see Food Services section below)
        - Change restaurant and bar layouts to ensure that all parties remain at least 6 feet (2 meters) apart (e.g., removing tables/stools/chairs, marking tables/stools/chairs that are not for use)
    - Elevators and Stairwells
        - Limit capacity, provide floor markings, and provide marked queuing areas to eliminate congregation
        - Use floor markings in elevator lobbies and near the entrance to escalators to reinforce social distancing of at least 6 feet (2 meters). Place decals inside the elevator to identify where passengers should stand, if needed.
        - Post signs reminding occupants to minimize surface touching. They should use an object (such as a pen cap) or their knuckle to push elevator buttons.
    - Entertainment Venues and Activities
        - Limit capacity in areas with performances, dancing, acting, and singing, and similar activities.
        - Provide social distancing between seating areas, such as by blocking out seats to allow individuals to remain at least 6 feet (2 meters) apart.
        - Limit capacity in areas with activities such as rock-climbing walls, zip-lines, mini golf, sports courts, jogging, skating, arcade rooms, and similar activities.
    - Casinos
        - Block out seats and gaming equipment to allow individuals to remain at least 6 feet (2 meters) apart
        - Limit customers' sharing of objects (e.g., items used in table games, dice) when possible, and clean and disinfect these objects between uses as much as possible
        - Set up physical barriers where it is difficult for individuals to remain at least 6 feet (2 meters) apart
    - Gyms
        - Provide social distancing of at least 6 feet (2 meters) between equipment, such as by blocking out or removing equipment

- Public Toilet Rooms
  - Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual.
  - Add physical barriers, such as plastic flexible screens, between toilet room sinks, stalls, and urinals, especially when they cannot be at least 6 feet (2 meters) apart.
  - Ensure that people standing in line can maintain a 6-foot (2-meter) distance from one another. Post signs or markers to help attendees maintain the appropriate physical distance of at least 6 feet (2 meters).
  - Clean public toilet rooms regularly using products from the EPA List N: Disinfectants for Coronavirus (COVID-19), at least twice per day (e.g., in the morning and evening or after times of heavy use).
  - Provide information on how to wash hands properly. Hang signs in toilet rooms.
- Gangways
  - Provide physical guides, such as floor markings and signage, to instruct passengers to maintain a 6-foot (2-meter) distance from one another
- Recreational Water Facilities (RWFs)
  - Reduce the bather load for each facility to meet social distancing requirements. When social distancing of at least 6 feet (2 meters) between bathers is not possible, such as in small whirlpool spas, RWFs should be used by the same family or traveling companions only. This can be accomplished by close monitoring. Exceptions to social distancing are permitted when necessary to:
    - Rescue a distressed swimmer, perform cardiopulmonary resuscitation (CPR), or provide first aid; or
    - Evacuate the water or pool deck due to an emergency.
  - Place seating area items located in or around RWFs, such as tables, chairs, loungers, sun beds, and poufs, 6 feet (2 meters) apart from each other to adhere to social distancing standards. These items can be grouped together for families and traveling companions.
  - Follow the social distancing protocols of 6 feet (2 meters) for lines to use slides and other interactive RWF areas.
- Access Points (such as dining room entrances, guest services, disembarkation points)
  - Ensure that crew and passengers maintain 6 feet (2 meters) of social distance while waiting for access.
- Signs and Messages
  - Post signs, in highly visible locations (such as at entrances and in toilet rooms), to promote steps that prevent the spread of the virus (such as practicing social distancing of at least 6 feet (2 meters), and properly wearing a cloth mask).

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider the use of wearable proximity alerting technology, e.g. proximity bands, to alert the wearer of social distancing infractions to assist with maintaining social distancing protocols.
- Implement additional social distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures.
  - Dining

        - Eliminate any self-serve food or drink options, such as buffets, salad bars, and drink stations. This limits the use of shared serving utensils, handles, buttons, or touchscreens and helps customers to stay seated and at least 6 feet (2 meters) apart from people who do not live in their household.
    - Elevators and Stairwells
        - Encourage occupants to take stairs when possible, especially when elevator lobbies are crowded or when only going a few flights.
        - Where feasible, designate certain stairwells or sides of stairwells as "up" and "down" to better promote social distancing of at least 6 feet (2 meters).
        - Use stanchions (for lobbies only; not inside elevators) or other ways to mark pathways to help people travel in one direction and stay 6 feet (2 meters) apart.
        - Consider limiting the number of people in an elevator.
        - Encourage escalator and elevator passengers to wash their hands and avoid touching their face after holding on to handrails or touching buttons.
        - Consider adding supplemental air ventilation or local air treatment devices in frequently used elevator cars.
    - Entertainment Venues and Activities, Gyms, and Spas
        - Limit to reservation only time slots or limit capacity.
    - Public Hand Washing Facilities
        - Make sure waste receptacles are emptied regularly.
    - Muster Drills
        - Conducted virtually or in a staggered manner to allow social distancing of at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family.
    - Signs and Messages
        - Provide announcements on preventing the spread of the virus in manner that is accessible to all passengers.

HVAC Systems

When indoors, ventilation mitigation strategies can help reduce viral particle concentration. The lower the concentration, the less likely viral particles can be inhaled into the lungs (potentially lowering the inhaled dose); contact eyes, nose, and mouth; or fall out of the air to accumulate on surfaces. Protective ventilation practices and interventions can reduce the airborne concentrations and reduce the overall viral dose to occupants.

Heating, Ventilation, and Air Conditioning (HVAC) preventive measures should be implemented to minimize the possibility of dispersing the COVID-19 virus through the air. A layered approach should be applied using more than one preventive measure.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure ventilation systems operate properly for the occupancy level for each space.
    - Make sure air filters are properly sized and within their recommended service life.
    - Inspect filter housing and racks to ensure appropriate filter fit and minimize air that flows around, instead of through, the filter.
- Ensure toilet room exhaust fans are functional and operating at full capacity.

- Ensure sufficient negative air pressure in medical centers, and predetermined isolation and quarantine cabins.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider closing exclusively indoor RWFs, due to ventilation concerns.
- Increase the introduction of outdoor air:
    - Open outdoor air dampers beyond minimum settings to reduce or eliminate HVAC air recirculation.
    - Open windows and doors, when weather conditions allow, to increase outdoor air flow. Do not open windows and doors if doing so poses a safety or health risk.
- Use fans to increase the effectiveness of open windows:
    - Avoid placing fans in a way that could potentially cause contaminated air to flow directly from one person to another.
- Rebalance or adjust HVAC systems to increase total airflow to occupied spaces when possible.
- Turn off any demand-controlled ventilation (DCV) controls that reduce air supply based on occupancy or temperature during occupied hours.
- Improve central air filtration:
    - Increase air filtration to as high as possible without significantly reducing design airflow. Increased filtration efficiency is especially helpful when enhanced outdoor air delivery options are limited.
        - Filters with a higher number of Minimum Efficiency Reporting Value (MERV) have higher efficiency and ability to capture particles from the air. High-Efficiency Particulate Air (HEPA) filters can achieve at least 99.97% removal of viral particles in the air.
- Consider portable high-efficiency particulate air (HEPA) fan/filtration systems to enhance air cleaning (especially in higher risk areas such as the medical center or areas frequently inhabited by people with a higher likelihood of having COVID-19 and/or an increased risk of getting COVID-19).
- Consider using ultraviolet germicidal irradiation (UVGI) as a supplemental treatment to inactivate SARS-CoV-2, especially if options for increasing room ventilation and filtration are limited. Upper-room UVGI systems can be used to provide air cleaning within occupied spaces, and in-duct UVGI systems can help enhance air cleaning of recirculated air inside central ventilation systems.

Food Services

Passenger interactive experiences include, but are not limited, to interactive cooking, culinary workshops and demonstrations, mixology/blending classes, and galley and other “behind the scene” tours.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Change restaurant and bar layouts to ensure that all customer parties remain at least 6 feet (2 meters) apart (such as removing tables, stools, and chairs or marking any that are not for use).
- Limit seating capacity to allow for social distancing of at least 6 feet (2 meters).
- Discourage crowded waiting areas by using phone app, text technology, or signs to alert patrons when their table is ready. Avoid using “buzzers” or other shared objects.

- Eliminate self-service food and drink options, such as self-service buffets, salad bars, and beverage stations.
- Provide eating utensils in a way that prevents handling by more than one person.
- Install physical barriers, such as sneeze guards and partitions in areas where it is difficult for individuals to maintain proper social distance of at least 6 feet (2 meters), such as serving stations and food pick up areas.
- Provide physical guides, such as tape on decks and signage, to remind individuals to maintain social distance of at least 6 feet (2 meters) where food and beverages are served.
- Provide and encourage outdoor dining and bar/beverage service options.
- Provide and encourage in-room passenger dining service.
- Limit any sharing of food, tools, equipment, or supplies by food workers, to the extent practicable.
- Ensure adequate supplies to minimize sharing of high-touch materials (e.g., serving spoons) to the extent practicable; otherwise, limit use of supplies and equipment by one group of food workers at a time and clean and disinfect between use.
- Avoid using or sharing of items that are reusable, such as menus, condiments, and any other food containers. Instead, use disposable menus, digital menus that can be disinfected between each use, online menus that can be retrieved on diners' personal cell phones, single serving condiments, and no-touch trash cans and doors.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider options for consumers to order ahead of time to limit the amount of time spent in the restaurant.
- Provide alternative meal services options, such as prepackaged grab-and-go meals, for consumption on open decks or in individual cabins to minimize risks associated with congregate indoor dining.
- Use touchless payment options as much as possible, if available. If pens are needed for some purposes, disinfect between uses and/or encourage customers to use their own pens.

Cleaning and Disinfection

Numerous researchers have studied how long SARS-CoV-2 can survive on a variety of porous and non-porous surfaces. On porous surfaces, studies report inability to detect viable virus within minutes to hours; on non-porous surfaces, viable virus can be detected for days to weeks.

Cleaning of visibly dirty surfaces followed by disinfection helps prevent COVID-19 transmission. Cleaning with products containing soap or detergent reduces germs on surfaces by removing contaminants and may also weaken or damage some of the virus particles, which decreases risk of infection from surfaces. Disinfecting (using EPA's List N) kills any remaining germs on surfaces, which further reduces any risk of spreading infection.

Additional information on cleaning and disinfecting on cruise ships can be found on CDC's Interim Guidance for Ships on Managing Suspected Coronavirus Disease 2019 and Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Prioritize cleaning and disinfecting high-touch surfaces. Examples of high-touch surfaces include, but are not limited to: pens, counters, shopping carts, tables, doorknobs, light switches, handles, stair rails, elevator buttons, desks, keyboards, phones, toilets, faucets, and sinks.
- Use disinfectant products from the EPA List N that are effective against COVID-19. Check that the EPA Registration number on the product matches the registration number in the List N search tool. See Tips on using the List N Tool.
  - If products on EPA List N: Disinfectants for Coronavirus (COVID-19) are not available, bleach solutions can be used if appropriate for the surface.
- For RWFs: Clean and disinfect frequently touched surfaces multiple times a day, and shared objects before and after each time they are used. For example: handrails, slides, and structures for climbing or playing; lounge chairs, tabletops, pool noodles, and kickboards; and door handles and surfaces of toilet rooms, handwashing stations, diaper-changing stations, and showers. (Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19 | CDC)

Shore Excursions & Transportation Services

Participating in shore excursions and group transportation increases a person's risk of getting and spreading COVID-19 by bringing people in close contact with others, often for prolonged periods. Additionally, participating in these activities in other communities and countries with high prevalence of COVID-19 further increases the risk of introduction of COVID-19 onto cruise ships.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Prohibit self-guided or independent exploration by passengers during port stops.
- Ensure all shore excursion tour companies facilitate social distancing to allow for at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, mask wearing, cleaning and disinfection, and other COVID-19 public health measures throughout the tour.
- Restrict passenger attendance so that proper social distancing of at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and risk mitigation protocols can be met.

Recommendation

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

- Limit shore excursions in foreign ports of call to countries listed as Level 1: COVID-19 Low in CDC's COVID-19 Travel Recommendations by Destination.

Embarkation/Disembarkation Procedures

Embarkation and disembarkation places large numbers of people in close proximity—including passengers, crew, and port personnel—in indoor and sometimes small, enclosed spaces (e.g., gangways, corridors, waiting

areas). This close proximity can increase the risk of introduction and transmission of COVID-19 onto cruise ships and into communities.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure embarkation and disembarkation procedures follow the processes outlined in their Phase 2A port agreements.
- Ensure there is a private screening area for people identified as needing additional medical screening during the embarkation and check-in process.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Stagger or schedule embarkation/disembarkation times.
- Provide touchless check-in/check-out processes.
- Install signage and floor marking reminders and predetermined and spatially identified queue areas inside port terminals and onboard ships for passengers who are embarking and disembarking.
- Ensure written notifications about COVID-19 prevention and control are presented before passengers reach the check-in point to give them enough time to review prior to check-in.
- Use touchless garbage cans or pails and cashless payment options when possible. Otherwise, exchange cash or card by placing payment in a receipt tray, if available, or on the counter.
- Make alcohol-based hand sanitizer available to passengers, crew, and port personnel in these areas.

EXHIBIT D

OMB Approved
Control No. 0920-1335
Exp. 10/31/2021

Application for a CDC COVID-19 Conditional Sailing Certificate

Eligibility:

As a condition of applying for a COVID-19 Conditional Sailing Certificate, a cruise ship operator must verify that it has completed the previous phases and remains in compliance with the requirements of CDC's Framework for Conditional Sailing. This includes, as further described in this application:

1. Receiving 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, as modified and extended, is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy;
2. Establishing adequate health and safety protections for crew members while building onboard laboratory capacity needed to test crew and future passengers (Phase 1);
3. Conducting laboratory testing for every crew member on a weekly basis or at other intervals as required by CDC after completing initial crew testing (Phase 2A);
4. Documenting the approval of all U.S. port and local health authorities where the ship intends to dock or make port during one or more simulated voyages or restricted passenger voyages (Phase 2A); and
5. Conducting at least one simulated voyage that insofar as practicable test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship, including having submitted an after-action report to the CDC (Phase 2B).
    a) In lieu of conducting a simulated voyage, cruise ship operator responsible officials have signed and submitted to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submitted to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

Instructions:

A cruise ship operator should submit this application and all supporting documentation at least 60 calendar days[1] prior to intending to commence restricted passenger operations. CDC will review and provide a written decision regarding the application on a timely basis.

To facilitate CDC's review, please ensure that the following materials are either included as part of this application or have been previously submitted to the CDC:

1. Statement of intent stating the name, carrying capacity for passengers and crew, itineraries, ports of call, length of voyages, and expected onboard or shoreside activities, for the cruise ship being certified for restricted passenger operations;
2. A copy of the United States Coast Guard Certificate of Inspection issued in accordance with 46 CFR § 2.01-5 that was in effect for the six months preceding this application;
3. Written agreement for all U.S. port and local health authorities where the cruise ship intends to dock or make port during a restricted passenger voyage; and
4. After-action report(s) detailing any deficiencies in health and safety protocols found or observed

[1] The 60-calendar day timeframe is suggested as a guideline. CDC will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

Application for a CDC COVID-19 Conditional Sailing Certificate

during at least one simulated voyage that describe how the cruise ship operator will address those deficiencies prior to commencing restricted passenger voyages.

CDC review of this application:

CDC will review this application and all accompanying documentation for completeness and accuracy. CDC will grant or deny this application, in whole or in part, based on its 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. CDC will notify the cruise ship operator of its decision in writing.

If CDC requires additional information to determine 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 that the application is incomplete, it may hold the application in abeyance pending the submission of such additional information as required by CDC to make such a determination.

CDC will assess the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate in regard to passenger and crew capacity, itineraries, ports of call, length of voyages, onboard or shoreside activities, or any other activity relating to passenger or crew operations. CDC will make decisions regarding these components based on scientific criteria such as vaccination coverage in travelers and U.S. communities, trajectory of the pandemic, and the cruise ship operator's continued success at mitigating COVID-19 onboard its cruise ships as demonstrated through at least one simulated voyage.

Applications that are denied in their entirety may be appealed administratively to the CDC Director. CDC will provide additional information regarding how to submit an appeal if it decides to deny an application in its entirety.

Amendments and modifications:

A cruise ship operator may seek to amend or modify a COVID-19 Conditional Sailing Certificate by submitting a proposed amendment or modification to CDC for review and determination. 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.

CDC may require or allow a cruise ship operator to amend or modify its COVID-19 Conditional Sailing Certificate after one has been issued 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. Such public health considerations may include improved vaccination coverage in travelers and U.S. communities, trajectory of the pandemic, and the cruise ship operator's continued success at mitigating COVID-19 onboard its cruise ship.

Denials of requests to amend or modify a COVID-19 Conditional Sailing Certificate may be appealed administratively to the CDC Director. CDC will provide additional information regarding how to submit an appeal if it denies a cruise ship operator's request to amend or modify a COVID-19 Conditional Sailing Certificate.

Application for a CDC COVID-19 Conditional Sailing Certificate

Revocation or suspension:

CDC may deny an application for a COVID-19 Conditional Sailing Certificate, or revoke or suspend a COVID-19 Conditional Sailing Certificate after one has been issued 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 those that affect cruise travel as a whole.

Reinstatement:

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 not limited to, its ships, facilities, vehicles, equipment, communications, manifests, and employee and passenger health records;
2. Conferring with the cruise ship operator, its responsible officials, or other persons under the cruise ship operator's employ or acting on behalf of the cruise ship operator; 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.

CDC COVID-19 Conditional Sailing Certificate Requirements

Cruise Ship Operator and Ship Information
Name of Cruise Ship Operator:
Name of Cruise Ship Parent Company:
Name of Cruise Ship:
Verification of Eligibility
Date of signed acknowledgement of No Sail Order Response Plan Completeness and Accuracy:
Effective date(s) of agreement with all U.S. port and local health authorities:
Date(s) of simulated voyage(s):
Date(s) "after-action" report(s) was/were submitted to CDC for each simulated voyage:
Date(s) attestation and vaccination plan and timeline were submitted to CDC in lieu of a simulated voyage:
Proposed Restricted Voyages

Application for a CDC COVID-19 Conditional Sailing Certificate

Date cruise ship operator intends to commence restricted passenger operations:
Proposed carrying capacity for passengers and crew:
Proposed length of voyage(s):
Proposed itineraries (attach additional sheets as needed):
Proposed ports of call (attach additional sheets as needed):
Proposed onboard activities (attach additional sheets as needed):
Proposed shoreside activities (attach additional sheets as needed):

CDC COVID-19 Conditional Sailing Certificate Application

Responsible Officials Information		
The Chief Executive Officer (or equivalent), Chief Compliance Officer (or equivalent), and the highest-ranking Medical Officer, of the cruise ship's operating company and all parent companies must provide their contact information and signatures below.		
Operating Company		
Chief Executive Officer (or Equivalent) of Operating Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email:	
Address:		
Chief Compliance Officer (or Equivalent) of Operating Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email:	
Address:		
Highest-Ranking Medical Officer of Operating Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email:	
Address:		
Parent Company		
Chief Executive Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email:	
Address:		
Chief Compliance Officer (or Equivalent) of Parent Company		

CDC COVID-19 Conditional Sailing Certificate Application

Last name:	First name:	Middle initial:
Title:		
Telephone number:	Email:	
Address:		
Highest-Ranking Medical Officer of Parent Company		
Last name:	First name:	Middle initial
Title:		
Telephone number:	Email:	
Address:		

Conditional Sailing Certificate Requirements

The Cruise Ship Operator must meet the requirements in this application prior to receiving permission to commence restricted passenger operations. These requirements apply as a condition of obtaining or retaining a COVID-19 Conditional Sailing Certificate and 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 under a COVID-19 Conditional Sailing Certificate at any time while these requirements remain in effect.

1.	☐	The cruise ship operator submitted a complete statement of intent stating the name, carrying capacity for passengers and crew, itineraries, ports of call, length of voyages, and expected onboard or shoreside activities, for the cruise ship that I intend to have certified for restricted passenger operations.
2.	☐	Documentation includes a copy of the United States Coast Guard Certificate of Inspection issued in accordance with 46 CFR § 2.01-5 that was in effect for the six months preceding this application.
General CSO Requirements		
3.	☐	Cruise ship operator submitted a response plan under the No Sail Order that is complete and accurate, including a signed Acknowledgement form.
4.	☐	Cruise ship operator submits the daily Enhanced Data Collection (EDC) During COVID-19 Pandemic form to CDC.
Phase 1 Requirements		
5.	☐	All crew were tested for COVID-19 via molecular tests approved for use by the FDA in a CLIA-certified lab approved by CDC.
6.	☐	The cruise ship developed onboard COVID-19 diagnostic testing capabilities for symptomatic travelers and their close contacts. Ship medical staff are competent in specimen collection and testing.
7.	☐	All land-based newly embarking crew are tested via molecular tests in a CLIA-certified lab. Specimens are collected on the day of embarkation and crew immediately begin a 14-day quarantine.

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8.	☐	The cruise ship has continued to follow their COVID-19 response plans developed under CDC's No Sail Order.
Phase 2A Requirements		
9.		The cruise ship operator has a written agreement with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a restricted passenger voyage. The written agreement specifically includes the name of the cruise ship listed in this application and meets the standards of the CSO and CDC's technical instructions for Phase 2A of CDC's CSO. The written agreement includes:
	☐	a) Port component (including a vaccination component) between the cruise ship operator and port authority to determine the number of cruise ships operating out of any single port to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak;
	☐	i. Include in this application the current status of the cruise ship operator's proposals regarding how it intends to incorporate vaccination strategies to maximally protect passengers and crew from introduction, amplification, and spread of COVID-19 in the maritime environment and land-based communities.
	☐	b) Medical care component between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and
	☐	c) Housing component between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and close contacts, identified from the day of embarkation through disembarkation for each voyage.
	☐	d) Any amendments or modifications to this written agreement have been notified and submitted to the CDC.
Phase 2B Requirements		
10.		At least simulated voyage was designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard the cruise ship. The following activities were at a minimum simulated onboard the ship:
	☐	a) Embarkation and disembarkation procedures, as approved by U.S. port and local health authorities as per the terms of the cruise ship operator's Phase 2A agreements, including procedures for terminal check-in.
	☐	b) Onboard activities, including seating and meal service at dining and entertainment venues.
	☐	c) Evacuation procedures.
	☐	d) Transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms.
	☐	e) Onboard and shoreside isolation and quarantine of passengers and non-essential crew, as per the terms of the cruise ship operator's Phase 2A agreements.

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	☐	f) Recreational activities that the cruise ship operator intends to offer as part of any restricted passenger voyages, e.g., casinos, spa services, fitness classes, gymnasiums.
	☐	g) Private-island shore excursions if any are planned during restricted passenger voyages.
	☐	h) Port of call shore excursions if any are planned during restricted passenger voyages.
11.		During the simulated voyage, the following laboratory testing was conducted:
	☐	a) Day of embarkation
	☐	b) Day of disembarkation
	☐	c) Symptomatic travelers and close contacts
	☐	d) At least 75% of all passengers provided their post disembarkation specimens for laboratory testing and these results were submitted to the CDC
12.	☐	Cruise ship operator submitted an after-action report detailing any deficiencies in its health and safety protocols and addressed how the cruise ship operator intends to address those deficiencies prior to commencing restricted passenger voyages.
Phase 2B Vaccination in Lieu of Simulated Voyage Requirements		
13.	☐	In lieu of conducting a simulated voyage, cruise ship operator responsible officials have signed and submitted to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submitted to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.
Phase 4 Acknowledgments		
14.		The cruise ship operator agrees to continue the following activities:
	☐	a) Submit the daily Enhanced Data Collection (EDC) During COVID-19 Pandemic form to CDC.
	☐	b) Adhere to requirements in CDC's Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew
	☐	c) Adhere to requirements in CDC's COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order.
	☐	d) Adhere to the written agreements of all U.S. port and local health authorities where the cruise ship intends to dock or make port during a restricted passenger voyage.
	☐	e) Adhere to the cruise ship operator's health and safety protocols, the efficacy of which were tested as part of a previous Phase 2B simulated voyage.
Certification and Signatures		
I certify under 18 U.S.C. § 1001, that I am submitting this form as part of an application to obtain permission to commence cruise ship passenger operations in U.S. waters and that the statements		

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contained herein are true and correct to the best of my knowledge and belief.

I acknowledge that any false or misleading statements or omissions may endanger health and safety, including but not limited to the loss of lives and other irreparable harm. Therefore, false, or misleading statements or omissions may result in criminal and civil actions for fines, penalties, damages, and imprisonment.

Chief Executive Officer (or Equivalent) of Operating Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Chief Compliance Officer (or Equivalent) of Operating Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Highest-Ranking Medical Officer of Operating Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Chief Executive Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Chief Compliance Officer (or Equivalent) of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
Highest-Ranking Medical Officer of Parent Company		
Last name:	First name:	Middle initial:
Signature:		Date:
For official use only:		

EXHIBIT E

Proposed Vaccination Goals in support of Cruise Resumption (April 26, 2021)

Purpose

The technical guidance for Phase 2A under the Conditional Sailing order requires " a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations." The guidance also requires "presentation of proposals…to incorporate vaccination strategies to maximally protect passengers…and land-based communities." The following is a high level, proposed approach to addressing these requirements. Industry believes that this approach will significantly reduce risk of COVID-19 transmission, allow for easier modifications of requirements in the CSO that are predicated on pre-vaccine conditions, and would facilitate cruise resumption in the U.S. by Summer 2021.

Guest Vaccinations

We are recommending all guests over the age of 18 be fully vaccinated before sailing. Based upon current market surveys, we believe that the vast majority of our guest bookings will be fully vaccinated before sailing. Children under the age of 18 will be subject to testing protocols. We recognize that a percentage of our guests may be unwilling to accept vaccine for various reasons.

Crew Vaccinations

We are committed to supporting the ability for all of our crewmembers to be vaccinated for cruises as they restart in the United States. We plan on using FDA/WHO approved vaccines. We are advising all crew to receive the vaccine in their home country as guided by their national health department. Any crew member who receives a non FDA/WHO approved vaccine will be regarded as non vaccinated and will be offered the approved vaccine once guidelines from the CDC are available.

Our intention is for all of our crew to be vaccinated. We recognize that a small percentage of crew may be unwilling to be vaccinated for various reasons such as medical or religious reasons, but we are committed to not sailing a vessel commercially out of the US unless at least 90% of our crew working on that vessel are vaccinated. Further, the cruise lines agree to institute strict antigen surveillance testing every three days for any unvaccinated crew members. Each ship will have a vaccination plan, tracking vaccine type, date of inoculation and will maintain all records associated with the crew vaccinations.

Conditions to the above

This crew commitment is dependent upon access to FDA/WHO vaccines which are not currently available commercially to cruise lines and for which government support is required. The cruise lines are in discussion with several Governors' offices in states in which vessels plan to operate, for such states to provide the necessary supply of surplus vaccine, and are working to arrange a mutually agreed path forward. Cruise lines will offer to pay for all vaccine and administration thereof at commercial rates. The foregoing will require the full support of the CDC, Department of Health and Human Services and the other representative agencies of this inter-agency working group.

This proposal is also on the basis that this commitment will be accompanied by (i) the significant relaxation of requirements contained within the CSO that are inconsistent with a largely vaccinated population, and (ii) the acceleration of timelines, streamlining of administrative steps and elimination of CDC stage-gating approvals, all to enable initial restart of commercial cruise operations by 4 July 2021.