

**qrulepubliccomments**

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**From:** Judy Woods [JWoods@iccl.org]  
**Sent:** Wednesday, March 01, 2006 5:31 PM  
**To:** qrulepubliccomments  
**Cc:** Angela Plott  
**Subject:** FW: DHHS FEDERAL REGISTER RIN 0920AA03  
**Importance:** High  
**Attachments:** ICCL Comments NPRM CDC 3-1-06.pdf

I am resending our comments in a pdf file, please use this document as our final submission. Thank you.

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**From:** Judy Woods  
**Sent:** Wednesday, March 01, 2006 5:08 PM  
**To:** 'qrulepubliccomments@cdc.gov'  
**Cc:** Angela Plott  
**Subject:** DHHS FEDERAL REGISTER RIN 0920AA03  
**Importance:** High

On behalf of the International Council of Cruise Lines (ICCL) we're submitting our comments on the Centers for Disease Control and Prevention's proposed rule on the Control of Communicable Diseases (70 FR 71892).

Please feel free to contact us if you have any problems with the attached file or if you have any questions concerning the submission

<<ICCL Comments NPRM CDC 3-1-06.pdf>>

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3/2/2006



INTERNATIONAL COUNCIL  
OF CRUISE LINES

**BEFORE THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**CONTROL OF COMMUNICABLE DISEASES  
PROPOSED RULE 42 CFR Parts 70 and 71**

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**COMMENTS  
OF THE  
INTERNATIONAL COUNCIL OF CRUISE LINES**

The International Council of Cruise Lines (ICCL) hereby responds to the captioned notice of proposed rulemaking, 70 Fed. Reg. 71892, November 30, 2005. ICCL is a non-profit trade association that includes 15 cruise line members, who comprise over 90% of the North American and international cruise industry, representing the vast majority of the berth capacity for passengers embarking from U.S. ports.<sup>1</sup> In 2005, the member lines of the ICCL will sail over 100 vessels and will carry more than eleven million passengers worldwide. Since 1968, ICCL and its predecessor organization have represented the interests of the cruise industry before domestic and international regulatory bodies.

The ICCL understands the U.S. government has a legitimate need to protect the health and safety of American citizens by preventing the introduction of communicable diseases into the U.S., and the importance of having protocols and procedures in place to ensure a swift response to a public health emergency.

In general, the cruise industry believes that any attempt to update the current quarantine regulations should be consistent with the new World Health Organization (WHO) International Health Regulations and apply to all modes of travel. For example, Canada has recently issued new quarantine regulations. They recognized the importance of including all conveyances, not just airplanes and ships in the health surveillance system. The proposed DHHS regulations do not address travel by bus or train.

Given the breadth of changes proposed to the Quarantine Regulations and the differences between the airline and cruise line industries, ICCL recommends that CDC establish a

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<sup>1</sup> ICCL member lines include: Carnival Cruise Lines, Celebrity Cruises, Costa Cruise Lines N.V., Crystal Cruises, Cunard Line., Disney Cruise Line, Holland America Line, NCL America, Norwegian Cruise Line, Princess Cruises, Radisson Seven Seas Cruises, Royal Caribbean International., Seabourn Cruise Line, Silversea Cruises and Windstar Cruises.

mechanism (e.g., government/industry working group) to meet throughout the year to ensure that the health and safety goals of the new regulations are faithfully and consistently implemented.

In addition, ICCL supports consolidation of U.S. government passenger data collection requirements. What is needed is a single, government-wide standard for passenger data collection and a single collection point to reduce duplication and inconsistent technical requirements. Historically, the maritime industry has always been an international business, and ICCL cruise lines travel throughout the world and call on over 30 U.S and 250 worldwide ports. Therefore, it is extremely important to have a standardized system of reporting and a universally recognized standard of protocols and procedures that is consistent with international standards.

The membership of the ICCL has serious concerns with several aspects of the Proposed Rule, which, for ease of discussion, are outlined and reviewed issue by issue.

### **Section 71.1 Scope and Definitions**

Under Section IV, Scope and Definitions, of the Summary of Proposed Changes, it states that:

the definition of ill persons has been modified to include all of the signs or symptoms commonly associated with diseases which provisional quarantine of quarantine may be necessary...Because reporting is dependent on recognition of an ill passenger by non-medical personnel and without the benefit of a medical examination, such as the flight crew, this definition relies on descriptive terms that are overt and commonly understood by lay persons.

The explanation given by the CDC for this very broad terminology of *ill person* is that it will ensure that all situations for which the CDC “must take action in order to prevent the introduction and spread of a communicable disease are reported”, since “the reporting of ill passengers relies on personnel without medical training.”

While the situation of having no medical personnel aboard may occur in other modes of the transportation industry, this is simply not the case for the cruise line members of ICCL. The ICCL cruise lines have taken an active role in addressing the quality of shipboard medical care. In 1995, the ICCL formed a Medical Facilities Working Group to develop industry-wide guidelines for the facilities, staffing, equipment and procedures in medical infirmaries on our cruise ships. This effort coincided with a similar effort by the American College of Emergency Physicians (ACEP), the nation’s leading and largest professional organization of such specialists, representing over 20,000 practicing physicians in the United States and abroad. ACEP’s Section of Cruise Ship and Maritime Medicine is specifically dedicated to training, education and research in the advancement of shipboard medical care.

As a result of the cooperative efforts between experienced cruise ship physicians and ACEP, all ICCL cruise line operators have agreed to meet or exceed the requirements of the ACEP Health Care Guidelines for Cruise Ship Medical Facilities. Included in the policies are procedures regarding 24-hour medical services and staff. Medical personnel are board certified or hold equivalent international certification, or have general practice and emergency or critical care experience. ICCL cruise lines have the ability to stabilize patients and/or give initial reasonable diagnostic and therapeutic intervention, and when necessary, have the ability to facilitate the evacuation of a seriously ill or injured patient. Cruise companies consider the size of the ship, proposed itineraries, and passenger demographics when outfitting shipboard medical infirmaries. Member cruise lines carry the necessary pharmaceutical drugs stipulated in categorized medical guidelines.

Although we applaud the CDC's abundance of caution approach for transportation entities with non-medical personnel, cruise lines with licensed medical professionals on board should not be subject to reporting based on these broad definitions. Instead, we recommend that cruise ships with licensed medical personnel on board should only have to file the WHO Maritime Declaration of Health. This report would provide the CDC Division of Quarantine and Global Migration the necessary information to make an informed assessment of the vessels health status. Also, it would provide standardization across the many countries that the vessels sail.

#### Definition of Ill Person

The regulations propose the following definition for *ill person*.

- (i) Has a temperature of 100.4° F (or 38°C) or greater accompanied by one or more of the following: Rash, swelling of the lymph nodes or glands, headache with neck stiffness, or changes in level of consciousness or cognitive function; or
- (ii) Has a temperature of 100.4° F (or 38°C) or greater that has persisted for more than 48 hours; or
- (iii) Has diarrhea, defined as the occurrence in a 24-hour period of three or more loose stools or of stools in an amount greater than normal (for the person); or
- (iv) Has one or more of the following: Severe bleeding, jaundice, or severe, persistent cough accompanied by bloody sputum, respiratory distress, or a temperature of 100.4° F (or 38°C) or greater; or
- (v) Displays other symptoms or factors that are suggestive of communicable disease, which the Director may describe in an order as the Director determines necessary.

We believe that the fairly broad syndromic definition of *ill person* as proposed by the CDC is overly broad and could, for example, include common influenza cases. In the cruise industry, where a vessel may carry from 200 to 4000 people, sail on voyages that last from 3 days to several months, there could often be instances where we might have a

number of people who report to the medical facilities on the ships at one time or the other, but will not necessarily have a communicable disease. On a typical 7 day cruise, ship medical staff will see only about 3-5% of guests. Of this very small percentage of guests, the majority of visits (90-95%), are for minor illnesses and can be treated onboard ship. In general, the small number of passenger visits to cruise ship medical facilities break down into the following categories:

- 26-29% report for respiratory problems. This includes seasickness, minor illnesses, colds and headaches.
- 12-18% report for minor injuries, including cuts and scrapes.
- Other: 12-16% - Gastrointestinal
  - 3-7% - Cardiovascular
  - 3-13% - Skin and subcutaneous tissue (i.e. sunburn)
  - 0.7% - Mental disorders

ICCL is concerned that under the proposed definition of *ill person* any positive declaration by the ship would place a ship at unwarranted risk for an exaggerated reaction as suggested in the CDC draft regulations to issue advisories, authorize tests and enforce quarantine. If the cruise industry were to notify the CDC of every instance as currently defined for *ill person*, the CDC will be inundated with the reporting of minor cases and innocuous data making it extremely difficult to pick out the infectious cases which would ultimately be counterproductive to the CDC's goals. Therefore, ICCL suggests the addition of the term, "illness suspicious for an infectious origin" to this definition.

### **Section 71.8 Report of death or illness on board ships**

As mentioned earlier, ICCL supports consolidating U.S. government passenger data collection requirements. Since the early 1970's, the cruise industry has participated in the CDC's Vessel Sanitation Program (VSP), which was established to minimize the risk of gastrointestinal illness (GI) on cruise ships. Ships with U.S. port itineraries are required to log and report the number of passengers and crew who have reported GI illness symptoms and who have requested anti-diarrheal medication. As ICCL is endorsing a single, government-wide standard for passenger data collected and a single collection point to reduce duplication and inconsistent technical requirements, for the cruise industry we recommend that the Division of Global Migration and Quarantine (DGMQ) use the existing CDC VSP electronic reporting system, known as the Automated Gastrointestinal Illness Surveillance System (GISS). In 2004, the VSP established the GISS electronic web-based reporting system, which allows cruise line personnel to submit routine and special GI case reports via-e-mail to VSP at the CDC. Cruise lines are expected to submit reports using this method. New data fields that will be required by DGMQ under the new quarantine regulations could be easily added to the GISS, and a central, single collection point within CDC could be established. There are some cruise lines that have developed electronic documentation and reporting systems that would send all this data electronically. These systems will be configured to add the data to the current GI reporting template.

### CDC Proposed Reporting Requirements of Ill persons

The ICCL has several concerns. While airlines are only required to report deaths and ill persons onboard, cruise lines will be required to report:

1. death or ill person,
2. death or ill person no longer on board,
3. case of or suspected case of communicable disease,
4. diarrhea,
5. febrile respiratory illness,
6. febrile rash illness,
7. febrile neurologic illness.

The term *Ill persons* should have one definition per Section 71.1, and any reporting requirements by the cruise industry to the CDC of *ill persons* should be consistent with that definition. The introduction of additional terms for reporting requirements, (e.g., febrile illnesses), are inconsistent, confusing and should be eliminated. Another problem is that CDC proposes the cruise industry to electronically report “any illness” in one section, and any “ill person” in another. This reporting requirement should be standardized to one definition, and ICCL recommends that the proposed regulation should be rewritten so that the cruise industry will report a death or ill person on board.

Under the proposed regulations, cruise lines must report different information at different times based on the location and itinerary. Given the large number of locations we visit and the wide variety of itineraries, these different reporting requirements are extremely confusing and unnecessarily burdensome. For example, if the vessel is on an international voyage and is traveling from one U.S. port to another U.S. port (e.g., Alaska cruises) they are required to report any case of, or suspected case of communicable disease. If the vessel is on an international voyage destined for a U.S. port they are required to report any death or ill person on board, or that had been on board during the 15 days preceding the arrival at a U.S. port.

Also new to the Quarantine Regulations is the requirement for a ship on an international voyage destined for the U.S. to report ill persons as “*as soon as such occurrences are made known to the ship’s commander*”. When in a U.S. port or between U.S. ports on an international itinerary, ill persons are reported “*immediately*” to the quarantine station.

Does this mean making several reports a day to the local quarantine station? This should be standardized to once a day. Again, what is important is the definition of *ill person*.

Using the broad, non-medical definition means that there could be at least 10 reports a day per ship based on types of cases seen in the emergency medical facilities. If this definition is not clarified, it would result in the ships’ medical personnel doing nothing more than making continuous reports! In addition, the proposed regulations call for reports to be filed even when there are no ill or dead passengers or crew. We propose that only positive reports of illness should be required from cruise vessels.

The proposed rule also has several time frames as to when the report needs to be made, which needs to be clarified and standardized. Sometimes reporting occurs as soon as it is known, sometimes it is immediately and sometimes it is 24 hours prior to arrival. These different timeframes are inconsistent, extremely confusing and should be standardized.

Under the proposed regulations, frequent reporting throughout the day will become necessary for cruises with Alaska itineraries because of the new requirement that a case or suspected case of communicable disease (colds, norovirus) be reported immediately to the quarantine station at the next U.S. port if the ship is traveling from a U.S. port to a U.S. port on an international itinerary. To standardize this reporting requirement, ICCL recommends that for all instances, vessels should have to report just once a day for positive illness reports only, but not less than 24 hours prior to arrival.

The proposed reporting requirements are summarized in the table below. As mentioned above, these requirements need to be streamlined and standardized. As mentioned above, ICCL proposes that there would be no reporting requirement if the ship had no ill or dead onboard, as the filing of no illness or problems is unnecessary.

<b>Type of Voyage or Ship Location</b>	<b>Report What</b>	<b>Report When</b>
International voyage destined for U.S.	death or ill person	As soon as known but not less than 24 hours prior to arrival
International voyage destined for U.S.	death or ill person no longer on board	Not stated
Traveling from U.S. port to U.S. port on international voyage	case of or suspected case of communicable disease	Immediately
In a U.S. port	death or ill person	Immediately
Before arrival (assume this is the first U.S. port on an international itinerary)	diarrhea, febrile respiratory illness, febrile rash illness, febrile neurologic illness for current cruise	24 hours prior to arrival, additional diarrhea cases at least 4 hours prior to arrival

**Section 71.9 Written plan for reporting of deaths or illness on board ships and designation of a shipline’s agent**

Under the proposed regulations, the CDC is proposing giving cruise lines 90 days for developing a written plan for reporting of disease (the number of cases, including zero, of diarrhea, febrile respiratory disease, febrile rash illness, or febrile neurologic illness) and an additional 90 days for implementation.

The ICCL membership believes that the proposed timeline of 90 days is problematic as it is simply not a long enough time period to reasonably expect a major transportation carrier such as a cruise line to write and establish a plan, and then implement the plan

across all of its vessels. The CDC proposed regulatory changes are substantial and wide-reaching, and sufficient time must be given to allow the transportation carrier to properly develop a plan for implementation. We propose cruise lines should have 6 months to develop the written plan, and another 3 months to implement it on their vessels.

### **Section 71.10 Passenger information**

Under the proposed Rule, CDC put forth that cruise lines will solicit information from each passenger or crewmember and the company will be able to maintain (and transmit) the data electronically for 60 days from the end of the voyage.

Before directly commenting on this Section, it is important to outline and review the current government rules and procedures that are currently in place to which the cruise industry is already compliant.

For many years, the cruise industry has worked closely with the US Coast Guard (USCG), and more recently the Department of Homeland Security (DHS) to submit passenger and crew manifests upon departure and prior to arrival in a U.S. port. As referenced in the CDC's *Regulatory Impact Analysis*, the Advance Passenger Information System (APIS) is a database system that was developed in 1988 to collect this manifest information.

Prior to September 11, 2001, ships or their agents notified the USCG Marine Safety Office/Captain of the Port zone, within 24 hours of the vessel's arrival via telephone, facsimile (fax) or electronic mail (e-mail). After September 11, 2001, the USCG established the National Vessel Movement Center (NVMC) ship arrival notification as part of the DHS initiative. The Notice of Arrival/Departure's (NOA/D) continued to be submitted via telephone, fax, or e-mail but were now required to be submitted to the NVMC, where watch personnel entered the information into a central database.

Effective October 2005, all cruise ships were required to submit NOA/Ds, and/or APIS information electronically, per CBP. It is important to note that as a result of the USCG and CBP working together to develop an authorized one-stop notification method, the eNOA/D application eliminates the need to submit the same information multiple times to multiple agencies.

The cruise industry applauds the initiatives taken by the USCG and CBP to coordinate their efforts to develop a unified electronic arrival and departure manifest system, meeting the requirements of both agencies. Currently, when an eNOA/D is completed properly and submitted, it provides all the information required by USCG and CBP regulations and eliminates the need to send separate notifications with slightly different information to multiple agencies. As mentioned above, it was developed to enable an

eNOA/D to be submitted directly to the NVMC via the web, thereby avoiding faxes, scanners, and telephones. It also provides a means for managing and storing recently submitted company, vessel, personnel, and arrival information. The eNOA/D application provides an easy-to-use and efficient method for reporting the vessel arrival and/or departure information required by the USCG and other Federal agencies for vessels visiting U.S. ports.

The fact is, the majority of the information required under CDC's proposed Rule will have already been collected from cruise vessels by the NVMC in the eNOA/D process (e.g., name, address, phone number, travel document and ports of call visited). The ICCL membership has some very serious concerns regarding any new proposal to set-up an alternative reporting system for another government agency to submit almost identical information. Therefore, we would strongly urge CDC to partner and coordinate with the CBP and the USCG to develop a methodology for adding needed data-fields and retrieval of this information from the existing eNOA/D system. If there is additional data that CDC will require, CDC can propose the changes be made directly to the eNOA/D through the addition of new data fields. Cruise lines are not using UN/EDIFACT format, they are submitting as required by the eNOA/D specifications, which is XML.

Regarding the proposal that cruise lines keep this manifest information electronically for 60 days, we suggest as an alternative that the NVMC route this data to CDC for each U.S. arrival notice and CDC keeps it in their system for as long as they want, like APIS does in their system. It also does not make sense for cruise companies to have to retain and/or send this information for 60 days after the voyage ends. The information is not going to change as far as our systems are concerned once the cruise guest arrives back into the U.S. ICCL has added specific comments below in red to the CDC proposed passenger information requirements:

#### Passenger and Crew Data (Manifests)

1. Full name (first, last, middle initial, suffix)  
**-APIS provides this as part of its current extract. Middle name/initial is optional.**
2. Emergency contact information  
**-APIS does not transmit this information. May or may not be captured by individual cruise lines.**
3. E-mail address  
**-APIS does not transmit this information. May or may not be captured by individual cruise lines. When asked, most people do not provide it. Most crew do not have email addresses.**
4. Current home address  
**-APIS does not transmit this information, however most cruise lines capture this information.**

5. Passport number or travel document number, including issuing country or organization  
**-APIS transmits this information, travel document type, document number and issuing country. Passport information is currently available only for non-U.S.**
6. Name of traveling companions or group  
**-Not currently required by APIS, nor is it captured by cruise lines.**
7. Flight information or ports of call  
**-Ports of call information collected for APIS as part of eNOA/D information. Flight information not required nor is captured by cruise lines.**
8. Returning flight or return ports of call  
**-APIS does not transmit this. Return flight information is collected by cruise lines, but only for air-sea guests.**
9. One of the following phone numbers (mobile, home, pager, or work)  
**--APIS does not transmit this information, and it may or may not be captured by cruise lines.**

In the cruise industry, most of the APIS information is obtained directly from the customer; however, there are instances where a travel agent may collect this information for the client. The point where this data is collected will vary from cruise line to cruise line. Some of the data elements are collected through the cruise line web-based reservations process, via a travel agent, or otherwise through the embarkation portal or once a passenger arrives at check-in. Therefore, information is collected at both the point of sale and point of departure.

A majority of the time, current data is captured electronically either by staff entering it from a passenger during embarkation check-in from a completed immigration form. Therefore, if the CDC draft regulations are enacted as currently proposed, wait time during embarkation will increase because of the additional information that will need to be added. Additional time will be needed at check-in to verify that the passenger information is in the system and/or correct. A special screen will have to be developed to access all required data easily. Given current cruise line procedures, these new requirements would significantly increase the time during check-in. In fact, cruise lines will have to completely rethink how check-in is conducted in order to just maintain current service levels. Cruise lines will have additional labor and IT costs as they will need to increase shoreside check-in staff as well as purchase additional hardware/software systems.

Passengers who compile the immigration questionnaire online prior to embarkation check-in will need to spend more time online filling in the required information. Currently about 25-30% of passengers complete the web-based check-in. Additional

costs will be incurred for modifying and reprinting the current immigration questionnaire and the online immigration form for self check-in will need to be redesigned and the computer based embarkation check-in program will also need to be redesigned. A program that generates the file from the database will need to be developed as well as a process to include the ports of call for the cruise with the passenger information. Wait time at check-in will be impacted if pieces of data are not collected prior to check-in. In addition, the cruise lines would incur IT expenses and Automation labor costs.

Currently, not all the cruise lines of the ICCL have the capability to ultimately collect and maintain this information. If a system were developed, information would have to be stored at the company's headquarters (which could be overseas), not on the cruise vessel as many of the individual vessel IT systems are not capable of retaining this information. IT systems can be developed to maintain and collect this data for 60 days, however, there will be substantial costs associated for items that include database, storage, development and ongoing maintenance support. A specific cost amount is not available at this time. As mentioned above, ICCL proposes the NVMC route the manifest data to CDC for each U.S. arrival notice and CDC keeps it in their system for as long as they want, similar to APIS. This alternative would allow CDC access to have the key information should an incident arise that calls for quarantine measures.

### **Section 71.11 Written plan for passenger information and designation of an airline or shipline agent**

The CDC is proposing that within 6 months, cruise lines must develop a written plan sufficient to ensure electronic transmission of passenger and crew information.

For the ICCL members, the proposed timeframes are NOT sufficient to develop and submit the plans described. First, the CDC requirements are not clear enough to submit an accurate plan within that timeframe. Then, considering some of the unknowns when it comes to technical requirements and the number of projects currently on deck, 6 months is not sufficient time to execute this transmission. Until we know the specific requirements and the application that it affects, this cannot be accurately answered. ICCL estimates that once the cruise industry receives through and well documented requirements and specifications from the CDC, it would take at a minimum 9 months. Then, once the plan is developed, depending on the complexity, it could take much longer to implement it across the entire fleet of ships.

To conclude, the membership of the ICCL believes it would be easier and more cost-effective for all concerned to combine or update the present eNOA/D with any additional passenger information requirements from the CDC. We recommend that CDC work with the USCG to arrange for access of eNOA/D similar to the USCS giving the CBP access to the data. The ability to leverage the eNOA/D process to gain efficiencies and take advantage of the functionality currently in place by the U.S. government is an opportunity which should not be missed.