

www.fitness.gov when it has been finalized.

The meeting that is scheduled to be held on May 5, 2015, is open to the public. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276-9567 no later than close of business on April 21, 2015, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to rsvp.fitness@hhs.gov or by calling (240) 276-9567. Registration for public attendance must be completed before close of business on April 28, 2015.

Dated: March 20, 2015.

Shellie Y. Pfohl,

Executive Director, Office of the President's Council on Fitness, Sports, and Nutrition, U.S. Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Requesting Federal Travel Restrictions for Public Health Purposes, Including for Viral Hemorrhagic Fevers

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

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is publishing this Notice to inform the public of the criteria CDC considers for requesting federal travel restrictions for public health purposes, including for use of the Do Not Board (DNB) list and Public Health Border Lookout records. Individuals with communicable diseases that pose a public health threat to travelers can be placed on this list to restrict them from boarding commercial aircraft arriving into, departing from, or traveling within the United States. This notice further describes the factors that HHS/CDC will consider in evaluating whether to request that an individual who may have been exposed to a hemorrhagic fever virus be placed on the DNB list, which is administered by the Department of Homeland Security (DHS). It also contains information for

individuals who have been placed on this list to respond to this decision in writing, if they believe the decision was made in error. This notice is effective immediately.

DATES: This notice is effective on March 27, 2015.

FOR FURTHER INFORMATION CONTACT: For information regarding this Notice:

Ashley A. Marrone, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-E03, Atlanta, GA 30329. For information regarding CDC operations related to this Notice: Travel Restrictions and Intervention Activity, ATTN.: Francisco Alvarado-Ramy, M.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-C-01, Atlanta, GA 30329. Either may also be reached by telephone 404-498-1600 or email travelrestrictions@cdc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Individuals with communicable diseases who travel on commercial aircraft can pose a risk for infection to the traveling public. In June 2007, HHS/CDC and DHS developed a public health DNB list, enabling domestic and international public health officials to request that individuals with communicable diseases who meet specific criteria, including having a communicable disease that poses a public health threat to the traveling public, be restricted from boarding commercial aircraft arriving into, departing from, or traveling within the United States.¹ The public health DNB list, administered by DHS and based on HHS/CDC's requests, is intended to supplement state and/or local public health measures to prevent individuals who are infectious, or reasonably believed to have been exposed to a communicable disease and may become infectious, from boarding commercial aircraft. Use of the list is limited to those communicable diseases that would pose a public health threat to travelers should the infected individual be permitted to board a flight. Once an individual is placed on the DNB list, airlines are instructed not to issue a boarding pass to the individual for any commercial domestic flight or for any commercial international flight arriving in or departing from the United States.

¹ CDC. *Federal air travel restrictions for public health purposes—United States, June 2007–May 2008*. MMWR 2008; 57:1009–12. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5737a1.htm>.

An individual is typically removed from the DNB upon receipt by HHS/CDC of the treating physician's or public health authority's statement (or other medical documentation) that the individual is no longer considered infectious, or lapse of the period that the individual is at risk of becoming infectious without development of symptoms.

Individuals included on the DNB list are assigned a Public Health Border Lookout ("Lookout") record that assists in ensuring that an individual placed on the DNB is detected if he or she attempts to enter or depart the United States through a port of entry. When this happens, officials from U.S. Customs and Border Protection (CBP), a component agency of DHS, notify HHS/CDC so that a thorough public health inquiry and evaluation can be conducted and appropriate public health action taken, as needed.

Requests for an individual to be placed on the public health DNB list with an associated Lookout record happen through a number of means, including: State or local public health officials contact the CDC Quarantine Station of jurisdiction, health-care providers make requests by contacting their state or local public health departments, and foreign and U.S. government agencies contact the CDC's Emergency Operations Center (EOC) in Atlanta. HHS/CDC may also request that DHS place an individual on the public health DNB and Lookout lists if HHS/CDC becomes independently aware of an individual who meets the placement criteria.²

HHS/CDC has refined the criteria that it initially considered, as published in the Morbidity and Mortality Weekly Report (MMWR) in 2008, and this notice describes the criteria CDC currently considers when making requests to DHS to include an individual on the DNB list and associated Lookout record. If an individual satisfies the first criteria and any of the three other criteria, then he/she may qualify to be placed on the list. Currently, HHS/CDC considers whether:

(1) The individual is known or reasonably believed to be infectious or reasonably believed to have been exposed to a communicable disease and may become infectious with a communicable disease that would be a public health threat should the individual be permitted to board a commercial aircraft or travel in a manner that would expose the public; and

² CDC. *Federal air travel restrictions for public health purposes—United States, June 2007–May 2008*. MMWR 2008; 57:1009–12. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5737a1.htm>.

(2) the individual is not aware of his or her diagnosis, has been advised regarding the diagnosis and is non-compliant with public health requests or has shown potential for non-compliance, or is unable to be located; or

(3) the individual is at risk of traveling on a commercial flight or of traveling internationally by any means; or

(4) the individual's placement on the DNB is necessary to effectively respond to outbreaks of communicable disease or other conditions of public health concern. For example, an individual's placement on the DNB may be considered when necessary to aid in the application of controlled movement³ or in the execution of a federal, state, or local quarantine, isolation, or conditional release order.

II. Authority

The DNB list and Lookout record are based on requests made by HHS/CDC regarding public health decisions and actions, and are administered by DHS. Under the Public Health Service Act, the Secretary of HHS is authorized to make and enforce regulations and take other actions necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or between states.⁴ Under its delegated authority, the HHS/CDC Division of Global Migration and Quarantine fulfills this responsibility through a variety of activities that may include operating quarantine stations at ports of entry, conducting routine public health screening, and administering quarantine regulations that govern the international and interstate movement of persons, animals, and cargo.⁵

Authority of DHS

Federal law authorizes CBP, U.S. Immigration and Customs Enforcement (ICE), and U.S. Coast Guard (USCG) officers to assist HHS by enforcing quarantine rules and regulations.⁶ In addition, other DHS Components such as the Transportation Security

Administration (TSA), relying on their existing authorities, may provide supportive roles to federal screening efforts designed to prevent the introduction and spread of communicable disease.

TSA has the authority to accept the services of, or otherwise cooperate with, other federal agencies including implementing the DNB list.⁷ Further, TSA may "develop policies, strategies, and plans for dealing with the threats . . . including coordinating countermeasures with appropriate departments, agencies, and instrumentalities of the United States."⁸ Consistent with this authority, TSA may assist another Federal agency in carrying out its authority in order to address a threat to transportation. These threats may involve passenger safety.⁹ In administering the DNB list, TSA relies on CDC to make public health findings as the basis for its request. As the medical authority for DHS,¹⁰ the Office of Health Affairs reviews and approves the medical appropriateness of HHS/CDC's request prior to DHS implementing HHS/CDC's request by placing the person on the DNB list.

III. Operations

Because of the urgency involved in restricting individuals with serious communicable diseases from boarding commercial aircraft, individuals might not be notified prior to their inclusion on the DNB list and associated Lookout record. When an individual is placed on the DNB list with an associated Lookout record, HHS/CDC advises in writing that the individual is temporarily restricted from traveling by commercial air carrier and provides the reasons why HHS/CDC has reached this decision. HHS/CDC interprets "temporarily restricted" to mean that the individual will remain on the lists until no longer considered to be infectious or at risk of becoming infectious. HHS/CDC's notification to the individual also explains that, while the individual is on these lists, travel by commercial aircraft is forbidden and any attempt to enter the United States through any port of entry will be stopped by CBP officials and that the individual will be referred for public health evaluation. If an individual cannot be located, HHS/CDC works with state and local public health officials to contact the individual through family or other contacts. HHS/CDC and DHS take great care to ensure personal medical information is safeguarded.

As part of its notification process HHS/CDC also asks the appropriate state or local health department to notify the individual directly, state the reasons for the placement on the DNB list and associated Lookout record, and provide the medical or public health requirements that must be satisfied to be removed from the lists. The primary consideration for requesting removal from the DNB list and associated Lookout record is CDC's determination that the individual is no longer considered to be infectious or at risk of becoming infectious; however, other factors may be taken into consideration including the individual's return to treatment, if applicable, and following public health recommendations. Once HHS/CDC receives documentation that these medical and other stated requirements have been met, it sends a request to DHS to lift the travel restrictions (both the DNB list and the Lookout record).¹¹ Once an individual is removed from the DNB list and the associated Lookout record is removed, a second notification letter is sent by HHS/CDC to the individual informing him or her that the public health travel restrictions have been removed and providing further recommendations on an as-needed basis (e.g., advising that the individual continue treatment, if applicable).

HHS/CDC's letter informing individuals that they have been placed on the DNB list and associated Lookout records invites individuals who believe that HHS/CDC's public health decision was made in error to submit a written response to the Director of HHS/CDC's Division of Global Migration and Quarantine and provide any supporting facts or other evidence supporting their belief. These operations and procedures will not change as a result of this Notice.

IV. Requesting Travel Restrictions for Viral Hemorrhagic Fevers

To date, the DNB list and associated Lookout records have been used primarily with respect to individuals with suspected or confirmed pulmonary tuberculosis (TB), including multidrug-resistant tuberculosis (MDR-TB), and a very small number with measles. However, travel restrictions are also applicable to other suspected or confirmed communicable diseases that could pose a public health threat during travel, including viral hemorrhagic fevers such as Ebola virus disease

³ See <http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html>.

⁴ 42 U.S.C. 264–265. The Secretary has promulgated implementing regulations at 42 CFR parts 70 and 71, administered by the CDC.

⁵ See generally U.S. Department of Health and Human Services Centers for Disease Control and Prevention, Public Health Screening at U.S. Ports of Entry: A Guide for Federal Inspectors (July 2007) (describing port of entry health screening procedures); 42 CFR part 70 (interstate quarantine regulations); 42 CFR part 71 (foreign quarantine regulations).

⁶ See 42 U.S.C. 97, 268(b).

⁷ 49 U.S.C. 106(l), (m), 114(m).

⁸ 49 U.S.C. 114(f)(3), (4).

⁹ See, e.g., 49 U.S.C. 114(h)(3).

¹⁰ 49 U.S.C. 321e(c)(1).

¹¹ In addition to contacting CDC, individuals seeking removal from the Public Health DNB may also seek assistance through the redress process established by DHS in 49 CFR 1560.205.

(Ebola). Ebola is a type of viral hemorrhagic fever that is often fatal in humans and nonhuman primates. Ebola can spread through human-to-human transmission, with infection resulting from direct contact (through broken skin or mucous membranes) with the blood, secretions, droplets, or other body fluids of infected people, and indirectly from contact with surfaces or items (such as needles) contaminated with such fluids.

With respect to viral hemorrhagic fevers, placement on the DNB list and associated Lookout record is requested for people known or suspected to have a viral hemorrhagic fever. Placement may also be requested for people without symptoms who have been exposed to a viral hemorrhagic fever, particularly if these individuals intend to travel against public health recommendations. Even though people without symptoms are not infectious, these restrictions are requested because of the possibility that symptoms could develop during travel, particularly long international flights. Exposure is determined through a CDC risk factor assessment using information available from a variety of public health, medical and other official sources. Examples of types of potential exposure to viral hemorrhagic fevers contained within the CDC risk factor assessment include the following. It should be noted that not all of these exposures may result in travel restrictions.

- Having been in a country with widespread Ebola virus transmission within the past 21 days and, although having had no known exposures, is showing symptoms
- Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of a person with Ebola while the person was showing symptoms
- Exposure to the blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen) of a person with Ebola while the person was showing symptoms without appropriate personal protective equipment (PPE) (see <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>)
- Laboratory processing of blood or body fluids of a person with Ebola while the person was showing symptoms without appropriate PPE or standard biosafety protections
- Direct contact with a dead body without appropriate PPE in a country with widespread Ebola virus transmission (see <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html>)
- Having lived in the immediate household and provided direct care to

a person with Ebola while the person was showing symptoms

- In countries with widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms, or with the person's body fluids, or any direct patient care in other healthcare settings
- Close contact in households, healthcare facilities, or community settings with a person with Ebola while the person was showing symptoms
 - Close contact is defined as not wearing appropriate PPE within approximately 3 feet (1 meter) of a person with Ebola while the person was showing symptoms
- Having brief direct contact (e.g., shaking hands), while not wearing appropriate PPE, with a person with Ebola while the person was in the early stage of disease
- In countries without widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms
- Traveled on an aircraft with a person with Ebola while the person was showing symptoms

Exposure risk factors, such as those just described, will be considered by HHS/CDC in their totality when determining whether an individual meets the first criteria for placement on the DNB List, as described in Section I of this notice. HHS/CDC would also consider other facts and information it may have to make a decision with respect to the other criteria, as described in Section I of this notice. It should be noted that all facts are considered when applying the criteria. Again, with the exception of the first criteria, not all of the other criteria need to be present for HHS/CDC to make a request to DHS to have an individual placed on DNB and Lookout.

HHS/CDC would also consider these risk factors when assessing an individual who has been in a country where outbreaks of viral hemorrhagic fevers were occurring and refuses to comply with a public health assessment, and otherwise meets the travel restriction criteria. Refusing to comply with a public health risk assessment in this situation could include refusing to provide relevant information that would allow public health officials to assess the exposure risk.

V. Provisions of This Notice

HHS/CDC will make requests of DHS based on the criteria in this notice effective immediately. Individuals who have had their travel temporarily

restricted as a result of placement on the DNB list and associated Lookout records may submit a written response to the Director, Division of Global Migration and Quarantine, if they believe that HHS/CDC has erred in its public health request to DHS. The response should be addressed to: Director, Division of Global Migration and Quarantine, ATTN: Travel Restriction and Intervention Activity, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E-03, Atlanta, GA 30329. Responses may also be faxed to CDC at (404) 718-2158 or emailed to travelrestrictions@cdc.gov.

As part of the response, individuals should include the reference number listed in the notification letter they received and any facts or other evidence indicating why they believe that HHS/CDC's public health request was made in error.

The policy and program operations described above will become effective on March 27, 2015.

Dated: March 24, 2015.

Sylvia M. Burwell,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0908]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the establishment and operation of clinical trial data monitoring committees.