# Addendum to the Technical Instructions for Medical Examination of Aliens

# Updated Screening for Communicable Diseases of Public Health Significance

October 6, 2008





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#### **Preface**

The Centers for Disease Control and Prevention (CDC) in the U.S. Department of Health and Human Services (HHS), has the authority to promulgate regulations that establish requirements for the medical examination of aliens before they may be admitted into the United States. Under section 212(a)(1) of the Immigration and Nationality Act (INA) (8 USC 1182(a)(1)), any alien determined to have a specified health-related condition is inadmissible to the United States. Aliens living outside the United States who have a specified health-related condition (see Background) are ineligible to receive a visa and may not be admitted into the United States. The overseas medical examination is a means of evaluating the health of aliens applying for entry into the United States and determining if they have a communicable disease of public health significance.

On October 6, 2008, HHS/CDC published an Interim Final Rule (IFR) for 42 Code of Federal Regulations (CFR) Part 34 – Medical Screening of Aliens that amended the definition of a communicable disease of public health significance in 42 CFR 34.2(b), the scope of the examination (42 CFR 34.3), and the evaluation criteria for tuberculosis in 42 CFR 34.3. Updates to the evaluation criteria for tuberculosis will be addressed as appropriate in a separate Addendum to the Technical Instructions for tuberculosis. The definition of communicable diseases of public health significance continues to include the diseases listed in the *Technical Instructions for Medical Examination of Aliens, June 1991*, and adds two new disease categories: (1) quarantinable diseases designated by Presidential Executive Order, and (2) diseases that meet the criteria of a public health emergency of international concern which require notification to the World Health Organization (WHO) under the revised International Health Regulations (IHR) of 2005.

HHS/CDC also amended the provisions that describe the scope of the medical examination for aliens by incorporating a more flexible, risk-based approach based on medical and epidemiologic factors. This approach will determine which diseases are included in the medical screening and testing of aliens in areas of the world that are experiencing outbreaks of specific diseases.

These instructions, which are an addendum to the *Technical Instructions for Medical Examination of Aliens, June 1991*, are for the use of panel physicians and consular officers who are evaluating aliens applying for immigrant or refugee status, as well as non-immigrants who are required to have an overseas medical examination, hereafter referred to as applicants.

#### **Background**

Applicants are inadmissible into the United States if they are determined 1) to have a communicable disease of public health significance; 2) to have a physical or mental disorder and behavior associated with the disorder that may pose, or has posed, a threat to the property, safety, or welfare of the applicant or others; 3) to have a history of a physical or mental disorder associated with behavior which posed a threat to the property, safety, or welfare of the applicant or others and which is likely to recur or lead to other harmful behavior; or 4) to be a drug abuser or addict.

Medical examinations, including a physical and mental evaluation, to determine whether an applicant may have such a health-related condition are authorized under section 232 of the INA (8 USC 1222). Under sections 212(a)(1) and 232 of the INA and section 325 of the Public Health Service (PHS) Act (42 USC 252), the HHS Secretary promulgates regulations to establish the requirements for the medical examination and to list the health-related conditions that make applicants ineligible for entry into the United States. Previous Part 34 regulations defined a "communicable disease of public health significance" by only listing eight specific diseases - active tuberculosis (TB), human immunodeficiency virus (HIV) infection, chancroid, gonorrhea, granuloma inguinale, lymphogranuloma venereum, infectious syphilis, and infectious leprosy (Hansen's disease).

Recent experience has demonstrated that a fixed list of diseases does not allow the flexibility to rapidly respond to unanticipated emerging or re-emerging outbreaks of disease. The ability to rapidly respond requires an approach based on prospective risks and consequences instead of a static list that does not reflect the potential for future outbreaks of novel diseases. Therefore, HHS/CDC is adding the following disease categories to the current list of communicable diseases of public health significance:

- 1) Quarantinable, communicable diseases specified by Presidential Executive Order, as provided under Section 361(b) of the PHS Act;
- 2) Any communicable disease that requires notification to WHO of an event that may constitute a public health emergency of international concern, pursuant to the revised IHR of 2005.

## Changes to the Screening for Communicable Diseases of Public Health Significance and Scope of the Overseas Medical Examination

Quarantinable diseases designated by Presidential Executive Order and diseases that meet the criteria of a public health emergency of international concern which require notification to WHO under the 2005 IHR have been added to the list of communicable diseases of public health significance.

A risk-based approach that uses medical and epidemiologic factors will be required for the overseas medical examination.

HHS/CDC will determine any additional medical screening, testing, and treatment for a communicable disease in a specific population in a specific geographic location and will provide that information to panel physicians.

Panel physicians should NOT screen for any of the additional communicable diseases of public health significance without a specific notification from HHS/CDC.

The definition of communicable diseases of public health significance continues to include the diseases listed in the *Technical Instructions of Medical Examination of Aliens, June 1991*, and adds the following diseases:

Quarantinable, communicable diseases specified by any Presidential Executive Order under Section 361(b) of the PHS Act. Executive Order 13295 of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the most recent list of quarantinable, communicable diseases, and includes the following:

- cholera
- yellow fever
- plague
- viral hemorrhagic fevers
- diphtheria
- infectious TB
- smallpox
- severe acute respiratory syndrome (SARS)
- influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic (e.g., avian H5N1 influenza virus)

# Any communicable disease that requires notification to WHO as an event that may constitute a public health emergency of international concern under the 2005 IHR includes—

- human influenza caused by a new subtype (e.g., A/H1, A/H3)
- poliomyelitis due to wild-type poliovirus
- SARS
- smallpox
- other diseases that require notification through the use of the 2005 IHR algorithm

Further information on the 2005 IHR diseases and algorithm is available at the following website:

 WHO http://www.who.int/csr/ihr/prepare/en/

Further information and updates on the required notifiable diseases are available at the following websites:

- CDC/Division of Global Migration and Quarantine (DGMQ) http://www.cdc.gov/ncidod/dq/health.htm
- WHO

http://www.who.int/csr/ihr/Case Definitions.pdf http://www.who.int/csr/disease/en/

#### Revision of the scope of the overseas medical examination

The scope of the overseas examination has been revised to include additional medical screening, testing, and treatment, in specific circumstances, for assessments performed outside the United States for the following disease categories:

- 1) quarantinable, communicable diseases specified by Presidential Executive Order, as provided under Section 361(b) of the PHS Act;
- 2) any communicable disease that requires notification to WHO of an event that may constitute a public health emergency of international concern, pursuant to the revised IHR of 2005

The additional medical screening, testing, and treatment for the disease categories above will be determined by HHS/CDC using a risk-based approach based on medical and epidemiologic factors. This risk-based approach will apply only to medical examinations outside the United States and only in those geographic areas where the risk is high.

Under the new risk-based approach, HHS/CDC may require aliens outside the United States applying for U.S. immigration to undergo additional screening, testing, and treatment for specific communicable diseases of public health significance. The screening will take into account the following medical and epidemiologic factors:

- seriousness of the disease's public health impact
- whether the emergence of the disease was unusual or unexpected
- risk of the spread of disease to the United States
- transmissibility and virulence of the disease

- impact of the disease at the geographic location of medical screening
- other specific pathogenic factors that would bear on a disease's ability to threaten the health and security of the United States (e.g., travel history of the applicant or population of concern)

HHS/CDC will consider diseases identified through the IHR algorithm as communicable diseases of public health significance when they meet one or more of the criteria above, and for any of the following:

- a threat exists for importation into the United States
- such diseases may potentially affect the health of the American public

Changes to the testing and treatment requirements will depend on the severity of the communicable disease of public health significance and the effect on a specific population at the time of the medical examination. HHS/CDC may require additional screening, including additional medical interviews, physical examination, laboratory testing, radiological examination, or other diagnostic procedures.

Screening, testing, and treatment for newly identified diseases as a part of the list of communicable diseases of public health significance will continue until HHS/CDC determines the particular situation does not warrant this designation, based on the following factors:

- results of disease investigations
- response efforts
- effectiveness of containment and control measures
- current determination or termination of the public health emergency of international concern by the Director General of WHO
- other medical and epidemiologic considerations as determined by HHS/CDC

HHS/CDC will be responsible for determining if additional medical screening, testing, and treatment are needed for a disease in a specific population in a specific geographic location and will directly provide this information to panel physicians. **Panel physicians should NOT initiate** additional requirements for medical screening, testing, and treatment without notification from HHS/CDC. In most instances, additional medical screening and testing may consist only of epidemiologic questions and further physical examination relating to the disease. Updates of the *Technical Instructions* on a specific disease and additional medical screening, testing, and treatment protocol for the disease will be made available at CDC/DGMQ's website: http://www.cdc.gov/ncidod/dq/technica.htm.

#### **Required Evaluation**

The required overseas examination consists of a medical history, physical examination, and screening/diagnostic testing.

The overseas examination will continue to consist of a medical history, physical examination, and screening/diagnostic testing and should include:

- inquiry regarding contact with a person who has or has had: a communicable disease of public health significance; signs and symptoms suggestive of the disease; prior diagnostic evaluation and/or treatment of the disease.
- physical examination for communicable diseases of public health significance including, but not limited to, evaluation for fever, inspection for lesions and rash, and palpation of lymph nodes.
- further testing performed as necessary to confirm a suspected diagnosis.

Background information on a specific disease, including diagnosis and treatment, is available at the following CDC and WHO websites:

http://www.cdc.gov/DiseasesConditions/

http://www.who.int/topics/en/

#### Additional Evaluation Under the Risk-Based Approach

Panel physicians should NOT initiate additional requirements for medical screening, testing, and treatment without notification from HHS/CDC.

HHS/CDC will alert panel physicians when new or additional screening, testing, and treatment protocols for communicable diseases of public health significance are issued. *Technical Instructions* for screening, testing, and treatment of the additional disease(s) under the risk-based approach will be provided to the panel physicians. Until these instructions are made available by HHS/CDC, the panel physicians should continue to follow the *Technical Instructions for Medical Examination of Aliens, June 1991*. Updates of new *Addendums to the Technical Instructions* with information on a specific disease and additional medical screening, testing, and treatment protocol for the disease will be made available at CDC/DGMQ's website:

http://www.cdc.gov/ncidod/dq/technica.htm.

#### **Reporting Results**

The required overseas examination consists of a medical history, physical examination, and screening/diagnostic testing.

The applicant diagnosed with a communicable disease of public health significance must be treated by using a standard treatment regimen, as noted in the CDC website, <a href="http://www.cdc.gov/DiseasesConditions/">http://www.cdc.gov/DiseasesConditions/</a>, before the medical report forms (i.e., Department of State forms, DS-2053 [DS-2054 for countries implementing the 2007 TB Technical Instructions] and DS-3026) are completed.

- any untreated communicable disease of public health significance is a Class A condition and must be noted on the DS-2053 or DS-2054 in the space under "Class A Conditions."
- any treated communicable disease of public health significance is a Class B Other condition and the box "Other" under "Class B Conditions" must be checked and specific disease(s) noted on the DS-2053 or DS-2054.
- abnormal history, findings and resulting interventions must be described in the "Remarks" section of the DS-3026.

#### **APPENDIX A: GLOSSARY OF ABBREVIATIONS**

CDC Centers for Disease Control and Prevention

CFR Code of Federal Regulations

DGMQ Division of Global Migration and Quarantine

DS Department of State

HHS Department of Health and Human Services

HIV Human immunodeficiency virus

IFR Interim Final Rule

IHR International Health Regulations

INA Immigration Nationality Act

PHS Public Health Service

SARS Severe acute respiratory syndrome

TB Tuberculosis

USC United States Code

WHO World Health Organization

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Centers for Disease Control and Prevention Interim Final Rule (IFR), iii (CDC), 4, 6. See also Department of Health and **Human Services** International Health Regulations (IHR), iii, iv, 1, 2 algorithm, 3 Chancroid, iv Leprosy, iv Cholera. See Quarantinable diseases Lymphogranuloma venereum, iv Classification Class A, 6 Notifiable diseases. See Communicable diseases of Class B, 6 public health significance Code of Federal Regulations (CFR), iii Overseas examination medical history, 4 Communicable diseases of public health physical examination, 4 significance, 3-6. See also Quarantinable diseases screening, iii, iv, 1–6 definition, iii, iv, 1 testing, iii, iv, 1-6 human influenza, 2 treatment, 1–6 poliomyelitis, 2 Quarantinable diseases, iii, iv, 1, 2 Department of Health and Human Services cholera, 1 (HHS), iii, iv, 1-3, 5 diphtheria, 1 infectious tuberculosis, 1 Department of State forms influenza, 1 DS-2053, 6 plague, 1 DS-2054, 6 severe acute respiratory syndrome, 1, 2 DS-3026, 6 smallpox, 1, 2 viral hemorrhagic fevers, 1 Diphtheria. See Quarantinable diseases vellow fever, 1 Division of Global Migration and Quarantine, 2, 5 Panel physicians, 1, 3, 5 Drug abuse/addiction, iv Plague. See Quarantinable diseases Granuloma inguinale, iv Poliomyelitis. See Communicable diseases of public health significance Gonorrhea, iv Presidential Executive Order, iv, 1, 2 Hansen's disease. See Leprosy Public Health Service (PHS) Act, iv, 1 Human immunodeficiency virus (HIV), iv Risk-based approach, iii, 1, 2, 5 Human influenza. See Influenza Severe acute respiratory syndrome (SAR). See Immigration and Nationality Act (INA), iii, iv Quarantinable diseases Influenza. See Quarantinable diseases Smallpox. See Quarantinable diseases human, 2

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