

Q and A's - Revision of 42 CFR Part 34 (Medical Examination of Aliens) Updated Screening for Communicable Disease of Public Health Significance – Interim Final Rule (IFR), October 6, 2008

What is the medical examination of aliens?

Aliens are screened for any “communicable disease of public health significance” and other inadmissible medical conditions to determine if they can enter the United States. These medical assessments are conducted by doctors (panel physicians in foreign countries and civil surgeons for those already in the U.S. who are applying for adjustment of status to permanent resident.) This helps to safeguard the American public from serious disease threats.

Who are considered aliens?

The Secretary of Health and Human Services has the legal authority to establish regulations outlining the requirements for the medical examination of aliens before they may be admitted into the United States. This authority is provided under Section 212(a)(1)(A) of the Immigration and Nationality Act (8 U.S.C. § 1182(a)(1)(A)) and Section 325 of the Public Health Service Act.

An alien is any person not a citizen or national of the United States. Some types of aliens include immigrant, refugee, asylee or parolee as defined below:

An **immigrant** is a person from another country admitted to the United States as a lawful permanent resident.

A **refugee** is any person who is outside his or her country of nationality who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution based on race, religion, nationality, particular social group, or political opinion.

An **asylee** is considered the same as a refugee, except that an asylee applies for asylum status either upon arrival at a U.S. port of entry or after entry into the United States.

A **parolee** is a person from another country who appears to be inadmissible to the inspecting officer, but is allowed into the United States for urgent humanitarian reasons or when his or her entry is determined to be for significant public benefit.

What changes have been made to the regulation?

1. CDC has amended the list of “communicable disease of public health significance.” Because diseases emerge as public health threats faster than updates can be made through regulation change, the following two categories of diseases have been added:
 - Quarantinable diseases designated by Presidential Executive Order - currently cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or re-emergent influenza (pandemic flu.)
 - Events that are reportable as a public health emergency of international concern (PHEIC) to the World Health Organization (WHO) under the International Health Regulations (IHR) of 2005 (currently polio, smallpox, SARS, influenza, and other public health emergencies of international concern.)
2. CDC has added a risk-based approach for aliens screened outside of the United States that is based on medical and epidemiologic factors, to determine when and where additional screening, testing and treatment for specific infectious diseases should be conducted.

3. CDC has updated screening and testing for tuberculosis to utilize current medical knowledge and practice.

Why is CDC revising the regulation on medical screening of aliens?

The previous regulation did not adequately address emerging and re-emerging diseases in immigrant or refugee populations. CDC has modernized parts of the regulation to help safeguard the American public from communicable diseases in regions of the world where large numbers of U.S.-bound immigrants and refugees reside. The previous regulation did not allow the flexibility to monitor for emerging infectious diseases or unanticipated outbreaks overseas such as SARS or a new pandemic influenza virus.

These changes also allow for a risk-based approach to medical screening and testing. This approach allows CDC to determine the appropriate response to additional diseases of public health significance. This approach provides a flexible, fair and practical means to address infectious disease threats among at-risk aliens without placing an undue burden on other applicants to enter the U.S.

Updates to the medical screening for tuberculosis requirements were needed for better case detection of tuberculosis. The previous regulation was outdated and did not reflect current medical knowledge and practice.

Will these revisions to the regulation apply to those aliens residing in the United States?

The regulation revisions to detect additional diseases of public health significance will only apply to medical examinations performed outside of the United States, and not affect applicants already within the United States who apply for adjustment of status.

Prior to these revisions, what diseases were considered a “communicable disease of public health significance?”

Active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, *lymphogranuloma venereum*, *granuloma inguinale*, and HIV infection.

Does this Interim Final Rule (IFR) remove HIV infection or any other illness from the list of “communicable disease of public health significance?”

No. This IFR does not remove any disease from the list of communicable diseases of public health significance. HIV remains an excludable condition for entry to the United States until Part 34 is further amended to remove HIV.

What happens when an applicant applying to enter the United States is determined to have a disease based on the revised definition of “communicable disease of public health significance”?

An applicant with a communicable disease of public health significance may or may not be immediately eligible to enter the United States depending on the severity or nature of their condition. Once an applicant receives treatment or recovers from their condition, they would be eligible to enter the United States if they are no longer a significant health risk to others and meet all other requirements.

Is there a waiver process if an applicant has a communicable disease of public health significance?

The Department of Homeland Security will continue to provide waivers for applicants with a communicable disease in special circumstances. The applicant may be able to enter the United States depending on the specific circumstances of their condition.

What is a risk-based screening approach and how will it work?

Risk-based screening uses medical and epidemiologic criteria to determine the risk to others due to an outbreak of disease. If the risk of transmission of disease to others is thought to be high enough, this would warrant the screening of aliens for this condition based on the location and severity of the event. Criteria considered include: the seriousness of the disease's public health impact; whether the disease emergence was unusual or unexpected; the transmissibility and virulence of the disease; disease impact at the geographic location of medical screening; and other specific pathogenic factors that threaten the health security of the United States. The disease or event will be considered a communicable disease of public health significance when it meets one of these criteria and it is determined to be strongly associated with the threat of importation and of having potential adverse effect on the health of the American public. This update is important since screening of aliens is not currently based on the risk level of disease transmission.

Why use a risk-based screening approach?

CDC is unable to forecast the constantly changing migration patterns of immigrants and refugees, but must have the flexibility to respond swiftly as unpredictable, problematic health and humanitarian crises arise. Public health officials cannot predict which type of communicable diseases will occur and where they will happen. Using a risk-based approach for medical screening can anticipate potential health risks by tailoring medical screening and testing to a geographical location and prevalence of disease.

How will panel physicians know when and how to screen and test for diseases designated under the risk-based approach?

CDC develops and writes the Technical Instructions for the Medical Examination of Aliens. These technical instructions are available on the CDC website. Their purpose is to instruct panel physicians on the process of medical screening and testing for medical conditions that would make applicants inadmissible for entry into the United States. Panel physicians will continue to use all current Technical Instructions to screen aliens, unless they are notified by CDC to screen for additional diseases designated through the risk-based approach. CDC will alert panel physicians when new screening, testing or treatment protocols are issued based on outbreaks or disease events. The risk-based system uses medical criteria to determine the origin, potential spread, and patterns of developing diseases to establish instructions on how long to screen and test for illness at a particular location. The CDC Technical Instructions for Medical Examination of Aliens, including the most current updates, which panel physicians must follow, are available to the public on the CDC website, located at the following Internet address:
<http://www.cdc.gov/ncidod/dq/technica.htm>.

Will the medical examination of all aliens overseas be affected each time HHS/CDC's risk-based analysis determines a disease requires additional screening?

The number of applicants affected will generally be restricted geographically to specific areas of concern. Thus, the risk-based process will respond to emerging threats, without overwhelming the entire health system with needless testing.

How will other new, emerging, or unknown diseases be added to the list of communicable diseases of public health significance?

The 2005 International Health Regulations (IHR) have a process to identify events of potential international public health concern from unknown causes or diseases that are not currently identified. CDC will apply the IHRs risk-based screening algorithm to these diseases or events to determine if aliens should be examined for these new or reemerging illnesses.

How is CDC changing the screening for tuberculosis?

The former outdated regulation required sputum (mucus coughed up from the lower airways) smears for anyone suspected of having tuberculosis. CDC has changed the regulation to agree with current medical guidelines that call for a mycobacterium culture, which is 3 times as sensitive as a sputum smear for detecting active tuberculosis. CDC is also requiring a chest x-ray examination for applicants under the age of 15 when there is a reason to suspect tuberculosis infection, and clarifying the use of tuberculin skin tests, or a test equivalent to these tests, in addition to using chest x-ray examinations. Health security for the United States will be enhanced by the use of these updated medical screening methods.