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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 34**

**[Docket No. CDC-2015-0045]**

**RIN 0920-AA28**

**Medical Examination of Aliens - Revisions to Medical Screening Process**

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

**ACTION:** Final Rule.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this final rule (FR) to amend its regulations governing medical examinations that aliens must undergo before they may be admitted to the United States. Based on public comment received, HHS/CDC did not make changes from the NPRM published on June 23, 2015. Accordingly, this FR will: revise the definition of communicable disease of public health significance by removing chancroid, granuloma inguinale, and lymphogranuloma venereum as

inadmissible health-related conditions for aliens seeking admission to the United States; update the notification of the health-related grounds of inadmissibility to include proof of vaccinations to align with existing requirements established by the Immigration and Nationality Act (INA); revise the definitions and evaluation criteria for mental disorders, drug abuse and drug addiction; clarify and revise the evaluation requirements for tuberculosis; clarify and revise the process for the HHS/CDC-appointed medical review board that convenes to reexamine the determination of a Class A medical condition based on an appeal; and update the titles and designations of federal agencies within the text of the regulation.

**DATES:** This rule is effective [INSERT DATE 60 DAYS AFTER PUBLICATION OF THIS FEDERAL REGISTER DOCUMENT].

**FOR FURTHER INFORMATION CONTACT:** Ashley A. Marrone, J.D., Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS E-03, Atlanta, Georgia 30329; telephone 1-404-498-1600.

**SUPPLEMENTARY INFORMATION:** The Preamble to this FR is organized as follows:

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#### **I. Public Participation.**

On October 6, 2008, HHS/CDC published an interim final rule (IFR) (73 FR 58047) to amend its regulations that govern medical examinations that aliens must undergo before they are admitted to the United States. HHS/CDC amended the definition of “communicable disease of public health significance” by adding (1) quarantinable diseases designated by Presidential Executive Order, and (2) those 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 (<http://www.who.int/ihr/en/>). These amendments to the definition of communicable disease of public health significance permitted a more flexible, risk-based approach to the medical examination,

based on medical and epidemiologic factors. The IFR also updated the screening requirements for tuberculosis to be consistent with current medical knowledge and practice. The public was invited to comment on these amendments; the comment period ended December 5, 2008. On October 20, 2008, HHS/CDC published correcting amendments (73 FR 62210) that corrected an omission in the IFR. This document clarified that an alien of any age in the United States who applies for adjustment of status to permanent resident shall not be required to have a chest x-ray examination unless their tuberculin skin test, or an equivalent test that shows an immune response to Mycobacterium tuberculosis, is positive. HHS/CDC received three comments to the IFR, two comments from the public and one comment from a professional organization. A summary of those comments and a response to those comments are found at Section IV, below.

On June 23, 2015, HHS/CDC published a notice of proposed rulemaking (NPRM) (80 FR 35899) that proposed to amend its regulations to (1) revise the definition of communicable disease of public health significance by removing chancroid, granuloma inguinale, and lymphogranuloma venereum as inadmissible health-related conditions for aliens seeking admission to the United States; (2) update the notification of the health-related grounds of inadmissibility to include proof of vaccinations to align with existing requirements established by the Immigration

and Nationality Act (INA) (8 U.S.C.A. 1101 et seq.); (3) revise the definitions and evaluation criteria for mental disorders, drug abuse and drug addiction; (4) clarify and revise the evaluation requirements for tuberculosis; (5) clarify and revise the process for the HHS/CDC-appointed medical review board that convenes to reexamine the determination of a Class A medical condition based on an appeal; and (6) update the titles and designations of federal agencies within the text of the regulation. Specifically, HHS/CDC sought comment on:

1. Whether infectious Hansen's disease (previously referred to in regulation as infectious leprosy), infectious syphilis and/or gonorrhea should be removed from the definition of communicable disease of public health significance;
2. Whether the definition of communicable disease of public health significance and the scope of the medical examination should be revised as proposed in this regulation;
3. Whether the statutory requirement that aliens demonstrate proof of vaccinations should be incorporated into the regulations as a notifiable medical condition. To further clarify this question, HHS/CDC did not request comment on the statutory language itself as HHS/CDC does not have the authority to alter statutory language. Rather, we were

interested in comment on the advisability of incorporating statutory language into regulations;

4. Whether the requirement that immigrants demonstrate proof of vaccination against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices (ACIP) should be limited to only those vaccines for which a public health need exists at the time of immigration or adjustment of status. CDC has previously published criteria for determining whether a public health need exists at the time of immigration or adjustment of status. See 74 FR 58634 (Nov. 13, 2009). HHS/CDC was not seeking comment on the criteria, but rather on the incorporation of this standard into the regulations;
5. Whether the definitions and evaluation criteria for mental disorders, drug abuse and drug addiction should be revised as proposed in this regulation;
6. Whether the requirements for evaluating the presence of tuberculosis in alien applicants should be clarified and revised as proposed in this regulation; and
7. Whether the process for convening a medical review board and reexamination of an alien by a medical review board should be revised as proposed in this regulation.

HHS/CDC received three public comments on the 2008 IFR and six comments on the 2015 NPRM, from individuals and associations. A

summary of those comments and responses to those comments are found at Section IV, below.

## **II. Background**

### **A. Legal Authority**

HHS/CDC is amending the regulation under the authority of 42 U.S.C. 252 and 8 U.S.C. 1182 and 1222.

### **B. Legislative and Regulatory History**

Beginning in 1952, the language of the Immigration and Nationality Act (INA) mandated that, among other grounds for inadmissibility, aliens "who are afflicted with any dangerous contagious disease" are ineligible to receive a visa and therefore are excluded from admission into the United States. In 1990, Congress amended the INA by revising the classes of excludable aliens to provide that an alien who is determined (in accordance with regulation prescribed by the Secretary of Health and Human Services) to have a communicable disease of public health significance shall be excludable from the United States. Immigration Act of 1990, Pub. L. No. 101-649, section 601, 104 Stat. 4978 January 23, 1990; INA section 212(a)(1)(A)(i), 8 U.S.C. 1182(a)(1)(A)(i) (effective June 1, 1991). At the time of the 1990 INA amendments, the following specific communicable illnesses rendered an alien inadmissible: active tuberculosis,

infectious syphilis, gonorrhoea, infectious leprosy, chancroid, lymphogranuloma venereum, granuloma inguinale, and human immunodeficiency virus (HIV) infection. HHS/CDC subsequently published a proposed rule that would have removed from the list all diseases except for active tuberculosis. 56 FR 2484 (January 23, 1991). Based on the review and consideration of public comments received on this proposal, HHS published an interim final rule retaining all communicable diseases on the list and committed its initial proposal for further study. See 56 FR 25000 (May 31, 1991). On October 6, 2008, HHS/CDC published an Interim Final Rule (IFR) announcing a revised definition of communicable disease of public health significance and revised scope of the medical examination in 42 CFR part 34. This IFR addressed concerns regarding emerging and reemerging diseases in alien populations who are bound for the United States. See 73 FR 58047 and 73 FR 62210.

With the 2008 revision to 42 CFR part 34, the definition of communicable disease of public health significance was modified to include two disease categories: 1) quarantinable diseases designated by Presidential Executive Order; and 2) a communicable disease that may pose a public health emergency of international concern in accordance with the International Health Regulations (IHR) of 2005, provided the disease meets specified criteria in addition to the list of specific

illnesses. Specific illnesses remaining as a communicable disease of public health significance were active tuberculosis, infectious syphilis, gonorrhea, infectious Hansen's disease (previously referred to in regulation as infectious leprosy), chancroid, lymphogranuloma venereum, granuloma inguinale, and HIV infection.

In response to a 2008 amendment to the INA, on July 2, 2009, HHS/CDC published a Notice of Proposed Rulemaking (NPRM) (74 FR 31798), which proposed two regulatory changes: 1) the removal of HIV infection from the definition of communicable disease of public health significance; and 2) removal of references to serologic testing for HIV from the scope of examinations. On November 2, 2009, HHS/CDC published a final rule, effective on January 4, 2010 (74 FR 56547), that removed HIV infection and testing for HIV infection from part 34 regulations.

### **III. Summary of the Final Rule**

HHS/CDC identified the need for this rulemaking through an annual retrospective review of its regulations. Executive Order 13563 "Improving Regulation and Regulatory Review" requires Federal agencies to periodically review existing regulations to eliminate those regulations that are obsolete, unnecessary,

burdensome, or counterproductive or revise regulations to increase their effectiveness, efficiency, and flexibility.

Through this final rule, HHS/CDC will revise 42 CFR part 34 to reflect modern terminology and plain language commonly used in medicine and science by public health partners in the medical examination of aliens. Likewise, we are revising part 34 to include text that accurately reflects the statutory and administrative changes that have occurred within the Federal Government regarding agencies and/or departments responsible for this process. These revisions will ensure regulations that govern the medical examination of aliens are based upon accepted contemporary scientific principles as well as current medical practices.

The following is a section-by-section summary of the changes to part 34:

#### Section 34.1 Applicability

HHS/CDC is replacing the acronym "INS" within 34.1(c) with "DHS" to best reflect the administrative changes that have occurred within the Federal Government regarding agencies and/or departments responsible for the medical examination of aliens.

#### Section 34.2 Definitions

In this final rule, HHS/CDC is revising the definitions of: CDC, Communicable disease of public health significance, Civil Surgeon, Class A medical notification, Class B medical notification, Director, Drug abuse, Drug addiction, Medical notification, Medical hold document, Medical officer, Mental disorder and Physical disorder.

Additionally, HHS/CDC is adding definitions for DHS and HHS and removing the definition of INS.

#### Section 34.2(a) CDC

The definition of CDC is updated to reflect the current official title of the Agency: Centers for Disease Control and Prevention, Department of Health and Human Services. In doing so, we removed "Public Health Services" from the definition.

#### Section 34.2(b) Communicable disease of public health significance

This provision now defines communicable disease of public health significance as both a specific list of diseases and categories of diseases for which all aliens are inadmissible to the United States. This final rule removes three uncommon bacterial infections associated with genital ulcer disease: chancroid, granuloma inguinale, and lymphogranuloma venereum,

from the specific list of communicable disease of public health significance as provided for in 42 CFR 34.2(b).

#### Section 34.2(c) Civil Surgeon

HHS/CDC has removed the specific language of "District Director" and "INS" from the definition of civil surgeon to align with the specific language of the definition of civil surgeon as provided for in Department of Homeland Security (DHS) regulations in 8 CFR Part 232. HHS/CDC is also removing "with not less than 4 years' professional experience" from the definition of civil surgeon. Through complimentary regulations promulgated by DHS at 8 CFR Part 232, the requirement of 4 years' professional experience for civil surgeons will remain in effect. This change removes a redundancy found in HHS/CDC regulation and does not affect a substantive change in policy. HHS/CDC will continue to consult with the Department of Homeland Security (DHS)/United States Citizenship and Immigration Services (USCIS) as needed, regarding recommendations for civil surgeon requirements. Therefore, the definition of civil surgeon means a physician designated by DHS to conduct medical examinations of aliens in the United States who are applying for adjustment of status to permanent residence or who are required by DHS to have a medical examination.

#### Section 34.2(d) Class A Medical Notification

HHS/CDC is amending the definition of Class A medical notification by incorporating statutory language requiring documentary proof of vaccination. This requirement is provided by section 341 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA) which amended Section 212 of the INA. Part 34 is updated to explicitly include the requirement for proof of vaccination as previously specified in the IIRIRA. See Pub. L. 104-208, Div. C, 110 Stat. 3009-546. Lack of proof of vaccination will result in the issuance of a Class A medical notification. This additional language will not change current practices, but simply reflects updated statutory language.

The definition also includes the vaccination exemption specifically provided in Section 212 of the INA for an adopted child who is 10 years of age or younger. This exemption is applicable if, prior to the admission of the child, an adoptive or prospective adoptive parent, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that the child will be vaccinated within 30 days of the child's admission, or at the earliest time that is medically appropriate. Execution of this affidavit will prevent a Class A medical notification from being generated for lack of

proof of vaccination. This additional language does not change current practices, but reflects updated statutory language.

#### Section 34.2(f) Director

The final rule updates the definition of Director to reflect the current official title of the CDC Director, as well as his/her delegation authorities.

#### Section 34.2 (g) DHS

We are adding DHS to the definitions in order to best reflect the administrative changes that have occurred within the Federal Government regarding agencies and/or departments responsible for the medical examination of aliens.

#### Section 34.2(h) Drug abuse and Section 34.2 (i) Drug addiction

HHS/CDC is revising the definitions of drug abuse and drug addiction to align with the definitions of "substance use disorders" and "substance-induced disorders," provided by the Diagnostic and Statistical Manual for Mental Disorders (DSM) published by the American Psychiatric Association (25). The DSM is the medical standard for the diagnosis of mental disorders and substance-related disorders and provides current diagnostic criteria based on the latest available evidence.

#### Section 34.2 (k) Medical Hold Document

This final rule updates the definition of Medical hold document by replacing "INS" with "DHS", replacing "Public Health Service" with "HHS/CDC" and replacing "quarantine inspector" with "quarantine officer."

#### Section 34.2 (l) Medical Notification

The final rule amends the definition of medical notification by adding proof of vaccination requirements as already provided by section 341 of the IIRIRA which amended Section 212 of the INA. This amendment updates part 34 to include the requirement for proof of vaccination that is currently specified in statute in the IIRIRA and for those ACIP-recommended vaccinations for which HHS/CDC determines, by applying criteria published in the Federal Register, a public health need exists at the time of immigration or adjustment of status. This is not a substantive change to the regulation, as it will not affect current practice.

Based on this update, medical notification, according to the INA, means a medical examination document issued to a consular authority or DHS by a medical examiner that includes the following additional language: "(2) Documentation of having received vaccination against "vaccine-preventable diseases" for an alien who seeks admission as an immigrant, or who seeks

adjustment of status to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the ACIP for which HHS/CDC determines, by applying criteria published in the Federal Register, there is a public health need at the time of immigration or adjustment of status.”

Section 34.2(m) Medical officer

The final rule removes “of the Public Health Service Commissioned Corps” from the definition of medical officer to reflect that a medical officer for these purposes is not required to be a member of the U.S. Public Health Service Commissioned Corps.

Section 34.2(n) Mental Disorder and 34.2(p) Physical Disorder

The final rule clarifies mental disorder as a currently accepted psychiatric diagnosis, as defined by the most recent edition of the DSM published by the American Psychiatric Association (17) or in another authoritative source as approved by the Director. This revision adds “most recent” to qualify the version of the DSM referenced in this definition and

clarifies the intent of HHS/CDC that such diagnoses align with current science and medical practice. This update also allows for the possibility of other authoritative sources to be used in the future based on the most current medical science and in the event that the DSM is no longer the accepted authoritative source for determining a psychiatric diagnosis.

The final rule defines physical disorder to mean a currently accepted medical diagnosis, as defined by the most recent edition of the Manual of the International Classification of Diseases, Injuries, and Causes of Death (ICD) published by the World Health Organization (26) or in another authoritative source as approved by the Director. HHS/CDC is adding "most recent version" to qualify the version of the ICD referenced in this definition and to be consistent with the current Section 212 of the INA. HHS/CDC also allows for the possibility of other authoritative sources to be used in the future based on the most current medical science and in the event that the ICD is no longer the accepted authoritative source for determining a physical diagnosis.

### c. Section 34.3 Scope of Examinations

This section applies to those aliens who are required to undergo a medical examination for U.S. immigration purposes. The scope of the examination outlines those matters that relate

to inadmissible health-related conditions and was revised in 2008 through an interim final rule. The 2008 interim final rule provided specific screening and testing requirements for those diseases that meet the current definition of communicable disease of public health significance in § 34.2(b) of 42 CFR part 34. This final rule further updates this section to incorporate statutory language requiring documentation for vaccine-preventable disease and HHS/CDC's understanding that ACIP vaccine recommendations should only be applied in an immigration context when a public health need exists.

In 2009, HHS/CDC published a final notice in the Federal Register, adopting proposed criteria that HHS/CDC intended to use to determine which vaccines recommended by the ACIP for the general U.S. population should be required for immigrants seeking admission into the United States or seeking adjustment of status to that of an alien lawfully admitted for permanent residence based on public health needs (74 FR 58634). These criteria became effective on December 14, 2009. Since then, HHS/CDC has relied on such criteria to determine which vaccines aliens must receive as part of the immigration medical screening process.

The 2015 NPRM proposed to formally incorporate a reference to this criteria into this final rule. HHS/CDC did not receive public comment in opposition of the incorporation. Therefore,

under this final rule, HHS/CDC has modified the regulatory text to reflect reference to these criteria where appropriate. We note that if there is a future need for HHS/CDC to reconsider these established criteria, HHS/CDC will solicit comments through publication in the Federal Register. In subsection (a)(2)(i), we have also inserted the word "current" in front of "physical or mental disorder" as stated in section 212 of INA.

Specific proposed revisions to Section 34.3(a)

The final rule revised § 34.3(a)(2) to include proof of vaccination requirements as provided by section 341 of IIRIRA of 1996 which amended Section 212 of the INA.

Specific proposed revisions to Section 34.3(e)

The final rule amends § 34.3(e)(1) to clarify the scope of examination requirements that apply to anyone who is required by DHS to have a medical examination for the purpose of determining their admissibility. The final rule adds § 34.3(e)(1)(v) "Applicants required by DHS to have a medical examination in connection with the determination of their admissibility into the United States."

The final rule includes the following changes to provide consistency in the required evaluation for tuberculosis: replace all references to "chest x-ray" in § 34.3(e) with "chest

radiograph"; clarify that § 34.3(e)(3)(ii) applies to aliens in the United States; and to remove the specific size of chest radiograph provided in § 34.3(e)(5). These changes reflect current medical terminology and technical practice.

The final rule amends § 34.3(e)(2)(iii) by removing "and HIV" to correct the typographical error in the current rule language and reflect that testing for HIV is no longer required. The requirement for serologic testing for syphilis will remain and the final rule includes language to allow the Director to test for other communicable diseases of public health significance (as defined) through technical instructions.

The final rule amends §§ 34.3(e)(3)(i) and 34.3(e)(3)(ii) to reflect the scope of currently available medical tests. The final rule replaces "positive tuberculin reaction" with "positive test of immune response to Mycobacterium tuberculosis antigens" in §§ 34.3(e)(3)(i) and 34.3(e)(3)(ii).

To allow HHS/CDC discretion to apply appropriate medical screening procedures, the final rule amends §§ 34.3(e)(3)(iii) and 34.3(e)(3)(iv) regarding application of tests of immune response by adding "as determined by the Director."

To allow for additional testing in medically appropriate circumstances, the final rule revises § 34.3(e)(4) by removing "subject to the chest radiograph requirement, and for whom the radiograph shows an abnormality suggestive of tuberculosis

disease," replaces "shall" with "may," and adds "based on medical evaluation." Thus, in the final rule, this revision reads: "All applicants may be required to undergo additional testing for tuberculosis based on the results of the medical evaluation."

To reflect current practice and INA statutory language, the final rule amends § 34.3(b)(2) by adding "or other relevant records" to ensure that all appropriate available medical documentation may be considered. Thus, in the final rule, this revision reads: "For the examining physician to reach a determination or conclusion about the presence or absence of a physical or mental abnormality, disease, or disability, the scope of the examination shall include any laboratory or additional studies that are deemed necessary, either as a result of the physical examination or pertinent information elicited from the alien's medical history or other relevant records."

The final rule includes language under § 34.3(f), transmission of records, to ensure that electronic submissions may be acceptable as provided by the Director. Finally, the final rule amends § 34.3(g)(4) by replacing "excludable" with "inadmissible" in § 34.3(g)(4) to reflect modern terminology.

#### d. Section 34.4 Medical notifications

The final rule revises § 34.4(b)(1)(ii) to include proof of vaccination requirements as provided by section 341 of the IIRIRA of 1996 which amended Section 212 of the INA and references criteria established by HHS/CDC and published in the Federal Register to determine which vaccines recommended by the ACIP will be required for U.S. immigration.

In addition, the final rule adds specific language regarding the exemption of vaccination requirements for an adopted child as provided in Section 212 of the INA.

e. Section 38.7 Medical and other care; death.

Under this section, the final rule replaces "INS" with "DHS" and replaces "Public Health Services" with "HHS" to reflect modern agency titles and appropriate authorities relating to this provision.

f. Section 34.8 Reexamination; convening of review boards; expert witnesses, reports

The final rule revises this section to clarify the reexamination and review board's process and improve the expediency of the process. The revisions include removing the requirement that one medical officer must be a board-certified

psychiatrist in cases where the alien's mental health is a basis for inadmissibility. The requirement for a board-certified psychiatrist is replaced with a requirement that the review board consist of at least one medical officer who is experienced in the diagnosis and treatment of the physical or mental disorder, or substance-related disorder for which the medical notification was made. Additionally, the final rule adds failure to present documented proof of having been vaccinated against vaccine preventable diseases as a basis for reexamination by the review board and adds clarifying language that the reexamination may be conducted, at the board's discretion, based on the written record.

#### **IV. Response to Public Comments**

##### **A. Summary of Public Comments to the 2008 IFR**

On October 6, 2008, HHS/CDC published an interim final rule (IFR) (73 FR 58047) to amend its regulations that govern medical examinations that aliens must undergo before they are admitted to the United States. HHS/CDC amended the definition of "communicable disease of public health significance" by adding (1) quarantinable diseases designated by Presidential Executive Order, and (2) those diseases that meet the criteria of a public health emergency of international concern which require notification to the World Health Organization (WHO) under the

International Health Regulations of 2005. These amendments to the definition of "communicable disease of public health significance" permitted a more flexible, risk-based approach to the medical examination, based on medical and epidemiologic factors. The IFR also updated the screening requirements for tuberculosis to be consistent with current medical knowledge and practice. The public was invited to comment on these amendments; the comment period ended December 5, 2008. On October 20, 2008, HHS/CDC published correcting amendments (73 FR 62210) that corrected an omission in the IFR. The correcting amendments clarified that an alien of any age in the United States who applies for adjustment of status to permanent resident shall not be required to have a chest x-ray examination unless their tuberculin skin test, or an equivalent test that shows an immune response to Mycobacterium tuberculosis, is positive. HHS/CDC received three comments to the IFR, two comments from the public and one comment from a professional organization. A summary of those comments and a response to those comments are found below.

One commenter urged HHS/CDC to remove HIV infection from the definition of communicable disease of public health significance, stating that HIV has specific methods of transmission and that the likelihood that an HIV positive

individuals would present an unusual risk of disease is extremely low.

Response: HHS/CDC thanks the commenter for this comment and notes that HHS/CDC removed HIV infection from the definition of communicable disease of public health significance by rulemaking in 2009. No changes were made to the final rule based on this comment.

A second commenter expressed concern that HHS/CDC was creating a double standard; an alien in the United States with a newly identified disease would not be found inadmissible, but an alien overseas with the same disease would be found inadmissible. With this double standard, aliens overseas would be encouraged to avoid overseas medical examinations and find ways to illegally enter the United States. The commenter suggested that the best way to avoid this situation would be to apply the same standards to medical examinations performed overseas and those performed in the United States. Finally, the commenter suggested that part 34 should be revised to clearly differentiate between overseas medical examinations and those in the United States.

Response: HHS/CDC notes that the final rule does make a distinction between the medical examinations performed for those aliens outside of the United States and those already in the United States applying for adjustment of status to that of a

lawful permanent resident. The distinction applies only to additional screening requirements for certain communicable diseases of public health significance where these diseases exist and for which importation into the United States would pose a threat as determined by the risk-based approach criteria. We reemphasize that both groups are required to undergo medical screening and the requirements for both groups are outlined in the regulation. No changes were made to the final rule based on this comment.

A third commenter expressed concern that the interim final rule did not include a provision to ensure that the public and the panel physicians are adequately notified of new and emerging diseases which could render individuals inadmissible and subject to an additional medical assessment. The commenter urged HHS to work closely with the Department of State to promptly notify the public of any health emergency or changes or additions to medical examinations through consular websites. Finally, the commenter was disappointed that HHS did not remove HIV infection as an inadmissible condition in this rulemaking.

Response: HHS/CDC notes that the regulation does contain a provision that all applicable additional requirements for medical screening and testing will be posted at the following internet address:

<http://www.cdc.gov/immigrantrefugeehealth/exams/ti/index.html>.

HHS/CDC also works closely with the Department of State to ensure that all changes or additions to the medical examination are communicated to affected consular posts, panel physicians, and to the public. Finally, HHS/CDC removed HIV infection from the definition of communicable disease of public health significance by rulemaking in 2009. No changes were made to the final rule based on this comment.

#### **B. Summary of Public Comments to the 2015 NPRM**

HHS/CDC received 6 comments from the public on this NPRM. A summary of the comments is provided here.

One commenter protested the proposal to remove the three STIs from the list of communicable diseases of public health significance. The commenter also disagreed with HHS/CDC's proposal to incorporate a more flexible, risk-based approach, based on medical and epidemiologic factors. The comment points to recent outbreaks of Ebola, Bird and Swine Flu and states that screening should be more vigilant, and that not having stricter screening risks an outbreak.

Response: HHS/CDC thanks the commenter for this comment and notes that in the 2008 IFR, HHS/CDC amended the definition of communicable disease of public health significance by adding (1) quarantinable diseases designated by Presidential Executive Order, and (2) those diseases that meet the criteria of a public

health emergency of international concern which require notification to the World Health Organization (WHO) under the International Health Regulations of 2005 which allows for screening of diseases in these categories which includes viral hemorrhagic fevers (such as Ebola) and flu that can cause a pandemic (including Bird and Swine variants). The addition of these categories of diseases along with the risk based approach allows HHS/CDC the ability to rapidly respond to unanticipated emerging or re-emerging outbreaks of disease and provides the framework to be able to screen and test individuals during disease outbreaks. HHS/CDC is confident that these changes will improve the ability of the United States to prevent the introduction and spread of infectious diseases, and to protect public health of the United States. No changes were made to the final rule based on this comment.

One commenter expressed concern about any disease coming off the list as these immigrants may be a public ward, and stated that individuals with HIV should not be allowed to immigrate to the United States. The commenter also noted that there was no comment period when HIV was removed from the list. The commenter also asks why unvaccinated children under ten should be allowed to immigrate to the United States. Finally, the commenter states that Ebola should be added to the list and that CDC should start thinking about other diseases to add to

the definition of communicable diseases of public health significance.

Response: HHS/CDC thanks the commenter for this comment and notes that HHS/CDC removed HIV infection from the definition of communicable disease of public health significance by rulemaking in 2009. As part of this process, HHS/CDC issued a notice of proposed rulemaking which received over 20,000 comments; the majority of which were in favor of removing HIV infection from the list.

Under the Immigration and Nationality Act (INA), children under 10 years of age who are adopted by U.S. citizens are exempt from vaccination requirements prior to entry into the United States. These children must receive vaccinations in the United States within thirty days upon arrival. The above exception and requirements are based on statutory language provided in the INA and cannot be changed by HHS/CDC regulations. This exception does not apply to any other children seeking an immigrant visa or adjustment of status to lawful permanent resident in the United States.

In the 2008 IFR, HHS/CDC amended the definition of "communicable disease of public health significance" by adding (1) quarantinable diseases designated by Presidential Executive Order, and (2) those diseases that meet the criteria of a public health emergency of international concern which require

notification to the World Health Organization (WHO) under the International Health Regulations of 2005. This allows for screening of diseases in these categories to be conducted during outbreaks and responses. Ebola and other hemorrhagic viral fevers are included in the current list of quarantinable diseases, and therefore are considered in the list of communicable diseases of public health significance. No changes were made to the final rule based on this comment.

One commenter stated that removing the STIs from the list of communicable diseases of public health significance may lead to decreased use of effective measures to prevent infection. This commenter stated that it is currently "too risky to the public good to downgrade the urgency of these types of preventable diseases." The commenter continued by stating that there have been countless occurrences of "plagues taking over nations and killing off much of the populations," and the commenter states that "there are many diseases that have not even been introduced yet and it is important to continue the current procedure in order to ensure nothing new 'plagues' the nation."

The same commenter stated that all aliens should be required to receive the same vaccinations that Americans receive. Additionally, the commenter submits that all immigrants should be revaccinated, as proof of vaccination from an

immigrant's home country may not be reliable. The commenter also provides two standards for vaccination. They are as follows:

1) if immigrating to the United States for economic reasons, the alien's standard of health should be comparable to the average resident of the United States.

2) if immigrating to the United States for medical treatment otherwise unobtainable in the alien's home country, the alien must be insured to prevent burden to the U.S. taxpayer.

Response: HHS/CDC notes that, according to the analysis provided in the notice of proposed rulemaking, the incidence and prevalence of these STIs is declining globally and so the potential for introduction and spread of these diseases to the U.S. population is considered to be low. By removing the three STIs which no longer pose a threat to public health, the medical examination will be able to focus on the other communicable diseases which are considered more serious risks to the United States. Removing these 3 STIs does not mean that persons will not be treated for these infections if the infections are found during the medical examination. Removing these 3 STIs means that persons who have these infections are no longer considered inadmissible to the United State. HHS/CDC has incorporated into its regulations the vaccination requirements that are included in statutory language provided in the Immigration and

Nationality Act (INA). Please see the relevant text of the INA at <http://www.uscis.gov/iframe/ilink/docView/SLB/HTML/SLB/act.html>. No changes were made to the final rule based on these comments.

Two commenters raised similar concerns regarding a statement made by HHS/CDC in the preamble of the 2015 NPRM regarding the inconclusive correlation between male circumcision and HIV prevention. Both commenters expressed disdain over the ethical, legal and methodological issues surrounding male circumcision as it relates to communicable disease. One commenter stated that some men from traditionally non-circumcising cultures [e.g. Hispanic/Latino communities] may read the NPRM and feel compelled to have themselves, and male children, circumcised in the belief that it may help them gain admittance to the U.S. Finally, both commenters concluded that any reference to male circumcision should be removed from the regulation.

Response: HHS/CDC thanks these commenters for their input. We note first that today's final rule does not contain any reference to male circumcision. Second, we clarify that whether a male is circumcised does not - and will not under today's final rule - have an effect on his medical examination or eventual admission into the United States. In the preamble language of the June 2015 NPRM, HHS/CDC stated: "... HIV

prevention strategies such as male circumcision may be playing a role, although definitive studies of this effect are still pending." This statement was made in addition to several other hypotheses which supported the underlying fact that "[D]eclining rates of these [STIs] are likely due to a variety of factors." Other factors considered and listed in the NPRM included: improved living conditions, better sanitation (e.g., availability of soap and water), condom use, educational efforts, improved recognition by physicians and treatment based on clinical presentation of sexually transmitted infections, treatment of sexual partners, as well as increased antibiotic usage for treatment of other unrelated conditions. No changes were made to the final rule based on these comments.

One commenter opposed the removal of the requirement that a board certified psychiatrist must be part of the review board for an alien seeking an appeal of mental disorder with associated harmful behavior. The commenter also supports updating the definitions of drug abuse, drug addiction and mental disorder to be made using current DSM standards and criteria. The commenter also indicated concerns about the policy behind the immigration medical examination and its likely discriminatory impact on those aliens with mental illness. The commenter further noted that the terms "drug abuser" and "drug addict" are obsolete and stigmatizing terms that require

replacement in order to meet current scientific understanding of substance use disorders.

Response: HHS/CDC thanks the commenter for the comments and support for updating the definitions of drug abuse, drug addiction and mental disorder to reflect current DSM standards and criteria. As acknowledged by the commenter, changes to the medical examination as it relates to mental illness, including revising the terms "drug abuser" and "drug addict," would require statutory language changes to the INA.

Regarding the comment about the requirement for a board certified psychiatrist to be a member of the review board, HHS/CDC notes that nothing in the regulations prevent the review board from including a board certified psychiatrist in mental disorder cases. However, the change in the regulation allows for another qualified mental health specialist to be on the review board in the event a board certified psychiatrist is not readily available. This allows for the review board process to proceed without any unnecessary delay that may affect the alien's immigration process. No changes were made to the final rule based on this comment.

## **V. Alternatives Considered**

This rulemaking is the result of HHS/CDC's annual retrospective regulatory review. Most of the amendments are

administrative and will result in minor changes to current guidelines for overseas medical examinations required of persons seeking permanent entry to the United States. Therefore, alternatives to these administrative updates were not considered.

However, as we stated in the proposed rule, when considering updates to the definition of communicable disease of public health significance, HHS/CDC looked at all of the specific diseases listed in the definition. As stated previously in the Preamble, in this rulemaking, HHS/CDC is revising the definition of communicable disease of public health significance by removing these three uncommon health conditions: chancroid; granuloma inguinale; and lymphogranuloma venereum.

We have decided not to remove infectious Hansen's disease (leprosy), gonorrhea, and/or infectious syphilis from the definition at this time. Our decision is based on epidemiological principles and current medical practice to assess these three diseases (infectious Hansen's disease, gonorrhea, and infectious syphilis). We believe that the medical examination provides the opportunity to screen for and treat these diseases, and, when identified in immigrants, provides a public health benefit to the United States as well as a health benefit to the individual. Further, while infection with these three diseases initially renders an alien

inadmissible to the United States, treatment is available upon identification, and once appropriately treated, aliens with these conditions are no longer inadmissible. Continued screening for these three diseases during the medical examination provides an opportunity to identify and treat disease in alien populations and thus provide a measure of public health protection to the general U.S. population. HHS/CDC will continue to assess each of these remaining diseases as a communicable disease of public health significance through further scientific review.

## **VI. Required Regulatory Analyses**

### **A. Executive Orders 12866 and 13563**

HHS/CDC has examined the impacts of the proposed rule under Executive Order 12866, Regulatory Planning and Review (58 FR 51735, October 4, 1993) and Executive Order 13563, Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011) (1,2). Both Executive Orders direct agencies to evaluate any rule prior to promulgation to determine the regulatory impact in terms of costs and benefits to United States populations and businesses. Further, together, the two Executive Orders set the following requirements: quantify costs and benefits where the new regulation creates a change in current practice; define qualitative costs and benefits; choose

approaches that maximize benefits; support regulations that protect public health and safety; and minimize the impact of regulation. HHS/CDC has analyzed the rule as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) and that the rule will create minimal impact (3,4).

This rule is not being treated as a significant regulatory action as defined by Executive Order 12866. As such, it has not been reviewed by the Office of Management and Budget (OMB).

There are two main impacts of this rule. First, we have updated the current regulation to reflect modern terminology, plain language, and current practice. Because there is no change in the baseline from these updates, no costs can be associated with these administrative updates to align the regulation with current practice.

Second, we have removed three sexually transmitted bacterial infections, chancroid, granuloma inguinale and lymphogranuloma venereum, from the definition of communicable disease of public health significance (5). In doing this, aliens seeking permanent entry to the United States (immigrants, refugees and asylees) will no longer be examined for these diseases during the mandatory medical examinations that are part

of the process of admission to the United States. The impact of dropping this portion of the examination is likely to be minimal. On the positive side, the physicians administering the exam will be able to focus on other areas of patient health. On the negative side, there is the potential for a negligible increase in the numbers of disease cases entering the United States. However, as we explain subsequently, this impact is likely to be small. Further, the costs associated with the current disease burden in the United States are also very limited. Therefore, the potential introduction of a very small number of cases will not change the current cost structure associated with the current disease burden.

As discussed in detail below, the three bacterial infections (chancroid, granuloma inguinale and lymphogranuloma venereum), are transmitted through sexual contact, have never been common in the United States and over the past two decades are observed to be increasingly rare throughout the world. Of the three conditions, only laboratory-diagnosed cases of chancroid are reportable in the United States, and since 2005 fewer than 30 chancroid cases annually were reported to CDC from the U.S. states and territories (6-23). While some U.S. cities (7) keep records of cases of granuloma inguinale and lymphogranuloma venereum, neither condition is included on the list of diseases reported to the CDC by clinicians and public

health departments (6). Online searches and a few available publications indicate that both conditions most typically occur in tropical and impoverished settings (i.e., with limited access to water, hygiene); and both conditions have become increasingly uncommon over time. A review of the literature published during the past five years identified only a handful of case reports on granuloma inguinale, and the vast majority of these cases were cases outside the United States (12-17). Sporadic small outbreaks of lymphogranuloma venereum have occurred over the past 10 years in Europe and the United States (18-20). The numbers of lymphogranuloma venereum cases are small, have been almost exclusively among men who have sex with men, and numbers are not systematically collected for country populations (18-20).

When HHS/CDC originally attempted to estimate the disease impact to calculate the cost associated with removing these three diseases, we tried to examine the disease rates in the regions or countries of origin of aliens seeking entry to the United States. In the most recent report from DHS, the Annual Yearbook of Immigration Statistics, DHS reports on the regions and countries of origin of aliens (24). Unfortunately, we have been unable to find disease data that correlates with DHS population data for region of origination of aliens (24). Data on chancroid, granuloma inguinale and lymphogranuloma venereum

are not systematically collected by any country outside of the United States either by specific countries or regions listed by DHS for aliens, or from the World Health Organization (WHO) (8, 22, 23). Ultimately, we were unable to correlate the originating regions of aliens entering the United States permanently (immigrants, refugees, and asylees) with the rates of the three diseases in the countries of origin.

Potential for onward transmission of these infections to the U.S. population is deemed to be extremely low. While we do not have country or region-specific rates for these diseases, our review of the literature supports the supposition that the potential introduction of additional cases into the United States by aliens is likely to have a negligible impact on the U.S. population. These primarily tropical infections can be prevented through improved personal hygiene (11) and protected sex (use of a condom) (12). New infections can be effectively treated and cured with a short, uncomplicated course of antibiotic therapy.

Economic analysis and cost results. HHS/CDC has determined that the costs associated with chancroid, granuloma inguinale and lymphogranuloma venereum are currently very low. Given the pattern of diminishing caseloads reported in the literature and available data (6-21), HHS/CDC projects that future costs will

remain low. A more detailed analysis as required by EO 12866 and 13563 can be found in the docket for this NPRM. A summary follows below.

Summary. There is no international disease incidence data available for chancroid, granuloma inguinale or lymphogranuloma venereum. There is some data available for numbers of cases of chancroid observed in the United States over a number of years (6) and DHS also provides data regarding the numbers of legal foreign residents in the United States (24). In the full analysis we used the chancroid data to estimate a range of costs to treat chancroid in the United States (6) at the highest and lowest caseloads observed. An estimated component for granuloma inguinale and lymphogranuloma venereum was added by assumption because of lack of either domestic or international data. The costs were then prorated to reflect the foreign population residing in the United States using DHS data (24).

Cost estimates were derived for three alternatives titled Low, High, and Extreme. The Low and High alternatives were based on the lowest (most recent) and highest reported caseloads of chancroid (6). The Extreme alternative is six times the highest rate of chancroid ever reported in the United States. Finally, often chancroid, granuloma inguinale, and lymphogranuloma venereum are co-morbid with other STIs, e.g.,

HIV, syphilis, or gonorrhea (6, 8, 21). Therefore costs are estimated to both treat cases with or without co-morbidity.

The results of the analysis are reported in Table 1. Because of a decreasing trend in reported cases, it is conservative to estimate the annualized burden of these diseases based on past reporting (i.e. the number of cases observed in the future are likely to continue decreasing). Further, it was assumed that all cases are detected and treated within the first year after arrival. As a result of these assumptions, monetized costs were unaffected by the choice of discount rate.

The results are not economically significant, i.e. more than \$100 million of costs and benefits in a single year.

Table 1. Annual Costs of Chancroid, Granuloma Inguinale, and Lymphogranuloma Venereum in Lawful Permanent Residents (LPRs): LOW, HIGH, and EXTREMELY HIGH caseload alternatives, in 2013 dollars			
	Alternatives		
Notes: 1) Per-case cost \$263.51. 2) Assumes LPRs are 0.4% of total population.	LOW (less than 1 case a year)	HIGH	EXTREMELY HIGH
<u>LPR</u> Total Annual Costs <u>50%</u>	\$18	\$2,122	\$12,731

<u>comorbidity</u>			
LPR Total Annual Costs <u>NO</u>	\$33	\$3,858	\$23,147
<u>comorbidity</u>			

Estimated benefits of this rule. The benefits to this rule are also qualitative. Aliens as well as the panel physicians and civil surgeons inherently benefit from having current, up-to-date regulations with modern terminology that reflects modern practice and plain language. The physicians administering the exam will be able to devote more time and training to other, more common and/or more serious health issues. The proposed changes do not impose any additional costs on aliens, panel physicians, or civil surgeons.

Comparison of costs and benefits. Given the potential impact of the rulemaking, we conclude that the benefits of the rule justify any costs. See Tables 2 and 3 below.

Table 2. Summary of the quantified and non-quantified benefits and costs for updates to the current regulation that reflect modern terminology, plain language, and current practice				
Category	Primary Estimate	Minimum Estimate	Maximum Estim	Source Citation

			e	(RIA, Preamble, etc.)
<b>BENEFITS</b>				
Monetized benefits	\$0 (7%)	\$0 (7%)	\$0 (7%)	RIA
	\$0 (3%)	\$0 (3%)	\$0 (3%)	
	\$0 (0%)	\$0 (0%)	\$0 (0%)	
Annualized quantified, but unmonetized, benefits	None	N/A	N/A	RIA
Qualitative (unquantified benefits)	Aliens as well as the panel physicians and civil surgeons inherently benefit from having current, up-to-date regulations with modern terminology that reflects modern practice and plain language.			RIA
<b>COSTS</b>				
Annualized monetized costs (discount rate in parenthesis) <sup>a</sup>	\$0 (7%)	\$0 (7%)	\$0 (7%)	RIA
	\$0 (3%)	\$0 (3%)	\$0 (3%)	
	\$0 (0%)	\$0 (0%)	\$0 (0%)	
Annualized quantified, but unmonetized, costs	None	N/A	N/A	RIA
Qualitative (unquantified) costs	None			RIA

Table 3. Summary of the quantified and non-quantified benefits and costs removing chancroid, granuloma inguinale, and lymphogranuloma venereum from the definition of communicable disease of public health significance				
Category	Primary	Minimum	Maximum	Source

	Estimate	Estimate	Estimate	Citation (RIA, Preamble, etc.)
BENEFITS				
Monetized benefits	\$0 (7%)	\$0 (7%)	\$0 (7%)	RIA
	\$0 (3%)	\$0 (3%)	\$0 (3%)	
	\$0 (0%)	\$0 (0%)	\$0 (0%)	
Annualized quantified, but unmonetized, benefits	None	N/A	N/A	RIA
Qualitative (unquantified benefits)	The physicians administering the exam will be able to devote more time and training to other, more common and/or more serious health issues.			RIA
COSTS				
Annualized monetized costs (discount rate in parenthesis) <sup>a,b</sup>	\$3,858 (7%)	\$3,858 (7%)	\$3,858 (7%)	RIA
	\$3,858 (3%)	\$3,858 (3%)	\$3,858 (3%)	
	\$3,858 (0%)	18 (0%)	\$23,147 (0%)	
Annualized quantified, but unmonetized, costs	None	N/A	N/A	RIA
Qualitative (unquantified) costs	None			RIA
<sup>a</sup> All costs of the rule are annual.				
<sup>b</sup> It was assumed that all cases occur within one year of arrival. Further, given the decreasing trend in reported cases in the United States, these estimates are likely to be conservative. As a result of these assumptions, the results do not change as a function of the discount rate.				

B. The Regulatory Flexibility Act

Under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), agencies are required to analyze regulatory options to minimize significant economic impact of a rule on small businesses, small governmental units, and small not-for-profit organizations. We have analyzed the costs and benefits of the final rule, as required by Executive Order 12866, and a preliminary regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. Based on the cost benefit analysis, we expect the rule to have little or no economic impact on small entities.

#### C. The Paperwork Reduction Act

The Paperwork Reduction Act applies to the data collection requirements found in 42 CFR part 34. The U.S. Department of State is responsible for providing forms to panel physicians, and the Department of Homeland Security is responsible for providing forms to civil surgeons to document the medical examination and screening information for aliens. The Office of Management and Budget (OMB) approved this data collection under OMB Control No. 1405-0113, which will expire on September 30, 2017. We note also that the medical examination form that civil

surgeons use is the I-693 and the OMB control number provided on the I-693 is 1615-0033, (expiration date 3/31/2017).

#### D. National Environmental Policy Act (NEPA)

HHS/CDC has determined that the amendments to 42 CFR part 34 will not have a significant impact on the human environment.

#### E. Executive Order 12988: Civil Justice Reform

HHS/CDC has reviewed this rule under Executive Order 12988 on Civil Justice Reform and determines that this final rule meets the standard in the Executive Order.

#### F. Executive Order 13132: Federalism

Under Executive Order 13132, if the rule would limit or preempt State authorities, then a federalism analysis is required. The agency must consult with State and local officials to determine whether the rule would have a substantial direct effect on State or local Governments, as well as whether it would either preempt State law or impose a substantial direct cost of compliance on them.

HHS/CDC has determined that this rule will not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

## G. The Plain Language Act of 2010

Under 63 FR 31883 (June 10, 1998), Executive Departments and Agencies are required to use plain language in all proposed and final rules. HHS/CDC has attempted to use plain language in this rulemaking to make our intentions and rationale clear. We received no public comment regarding plain language.

## VII. References

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**List of Subjects in 42 CFR Part 34**

Aliens, Health care, Medical examination, Passports and visas, Public health, Scope of examination.

For the reasons discussed in the preamble, the Centers for Disease Control and Prevention, Department of Health and Human Services revises 42 CFR Part 34 to read as follows:

PART 34 - MEDICAL EXAMINATION OF ALIENS

Sec.

- 34.1 Applicability.
- 34.2 Definitions.
- 34.3 Scope of examinations.
- 34.4 Medical notifications.
- 34.5 Postponement of medical examination.
- 34.6 Applicability of Foreign Quarantine Regulations.
- 34.7 Medical and other care; death.
- 34.8 Reexamination; convening of review boards; expert witnesses; reports.

Authority: 42 U.S.C. 252; 8 U.S.C. 1182 and 1222.

**§ 34.1 Applicability.**

The provisions of this part shall apply to the medical examination of:

- (a) Aliens applying for a visa at an embassy or consulate of the United States;
- (b) Aliens arriving in the United States;
- (c) Aliens required by DHS to have a medical examination in connection with the determination of their admissibility into the United States; and
- (d) Aliens applying for adjustment of status.

**§ 34.2 Definitions.**

As used in this part, terms shall have the following meanings:

(a) CDC. Centers for Disease Control and Prevention, Department of Health and Human Services, or an authorized representative acting on its behalf.

(b) Communicable disease of public health significance. Any of the following diseases:

(1) Communicable diseases as listed in a Presidential Executive Order, as provided under Section 361(b) of the Public Health Service Act. The current revised list of quarantinable communicable diseases is available at <http://www.cdc.gov> and <http://www.archives.gov/federal-register>.

(2) Communicable diseases that may pose a public health emergency of international concern if it meets one or more of the factors listed in §34.3(d) and for which the Director has determined a threat exists for importation into the United States, and such disease may potentially affect the health of the American public. The determination will be made consistent with criteria established in Annex 2 of the International Health Regulations (<http://www.who.int/csr/ihr/en/>), as adopted by the Fifty-Eighth World Health Assembly in 2005, and as entered into effect in the United States in July 2007, subject to the U.S. Government's reservation and understandings:

(i) Any of the communicable diseases for which a single case requires notification to the World Health Organization (WHO) as

an event that may constitute a public health emergency of international concern, or

(ii) Any other communicable disease the occurrence of which requires notification to the WHO as an event that may constitute a public health emergency of international concern. HHS/CDC's determinations will be announced by notice in the Federal Register.

(3) Gonorrhea.

(4) Hansen's disease, infectious.

(5) Syphilis, infectious.

(6) Tuberculosis, active.

(c) Civil surgeon. A physician designated by DHS to conduct medical examinations of aliens in the United States who are applying for adjustment of status to permanent residence or who are required by DHS to have a medical examination.

(d) Class A medical notification. Medical notification of:

(1) A communicable disease of public health significance;

(2) A failure to present documentation of having received vaccination against "vaccine-preventable diseases" for an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles,

rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which HHS/CDC determines, by applying criteria published in the Federal Register, there is a public health need at the time of immigration or adjustment of status. Provided, however, that in no case shall a Class A medical notification be issued for an adopted child who is 10 years of age or younger if, prior to the admission of the child, an adoptive parent or prospective adoptive parent of the child, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that, within 30 days of the child's admission, or at the earliest time that is medically appropriate, the child will receive the vaccinations identified in the requirement.

(3) (i) A current 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 alien or others;

(ii) A history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and

which behavior is likely to recur or lead to other harmful behavior; or

(4) Drug abuse or addiction.

(e) Class B medical notification. Medical notification of a physical or mental health condition, disease, or disability serious in degree or permanent in nature.

(f) DHS. U.S. Department of Homeland Security.

(g) Director. The Director of the Centers for Disease Control and Prevention or a designee as approved by the Director or Secretary of Health and Human Services.

(h) Drug abuse. "Current substance use disorder or substance-induced disorder, mild" as defined in the most recent edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM) as published by the American Psychiatric Association, or by another authoritative source as determined by the Director, of a substance listed in Section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802).

(i) Drug addiction. "Current substance use disorder or substance-induced disorder, moderate or severe" as defined in the most

recent edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM), as published by the American Psychiatric Association, or by another authoritative source as determined by the Director, of a substance listed in Section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802).

(j) Medical examiner. A panel physician, civil surgeon, or other physician designated by the Director to perform medical examinations of aliens.

(k) Medical hold document. A document issued to DHS by a quarantine officer of HHS at a port of entry which defers the inspection for admission until the cause of the medical hold is resolved.

(l) Medical notification. A medical examination document issued to a U.S. consular authority or DHS by a medical examiner, certifying the presence or absence of:

- (1) A communicable disease of public health significance;
- (2) Documentation of having received vaccination against "vaccine-preventable diseases" for an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles, rubella, polio,

tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which HHS/CDC determines, based upon criteria published in the Federal Register, there is a public health need at the time of immigration or adjustment of status. Provided, however, that in no case shall a Class A medical notification be issued for an adopted child who is 10 years of age or younger if, prior to the admission of the child, an adoptive parent or prospective adoptive parent of the child, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that, within 30 days of the child's admission, or at the earliest time that is medically appropriate, the child will receive the vaccinations identified in the requirement;

(3) (i) A current 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 alien or others;

(ii) A history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior;

(4) Drug abuse or addiction; or

(5) Any other physical or mental condition, disease, or disability serious in degree or permanent in nature.

(m) Medical officer. A physician or other medical professional assigned by the Director to conduct physical and mental examinations of aliens on behalf of HHS/CDC.

(n) Mental disorder. A currently accepted psychiatric diagnosis, as defined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association or by another authoritative source as determined by the Director.

(o) Panel physician. A physician selected by a United States embassy or consulate to conduct medical examinations of aliens applying for visas.

(p) Physical disorder. A currently accepted medical diagnosis, as defined by the current edition of the Manual of the International Classification of Diseases, Injuries, and Causes of Death published by the World Health Organization or by another authoritative source as determined by the Director.

**§ 34.3 Scope of examinations.**

(a) General. In performing examinations, medical examiners shall consider those matters that relate to the following:

- (1) Communicable disease of public health significance;
- (2) Documentation of having received vaccination against "vaccine-preventable diseases" for an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which HHS/CDC determines there is a public health need at the time of immigration or adjustment of status.

Provided, however, that in no case shall a Class A medical notification be issued for an adopted child who is 10 years of age or younger if, prior to the admission of the child, an adoptive parent or prospective adoptive parent of the child, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that, within 30 days of the child's admission, or at the earliest time that is medically appropriate, the child will receive the vaccinations identified in the requirement;

(3) (i) A current 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 alien or others;

(ii) A history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior;

(4) Drug abuse or drug addiction; and

(5) Any other physical or mental health condition, disease, or disability serious in degree or permanent in nature.

(b) Scope of all medical examinations. (1) All medical examinations will include the following:

(i) A general physical examination and medical history, evaluation for tuberculosis, and serologic testing for syphilis.

(ii) A physical examination and medical history for diseases specified in §§34.2(b) (1), and 34.2(b) (4) through 34.2(b) (10).

(2) For the examining physician to reach a determination and conclusion about the presence or absence of a physical or mental abnormality, disease, or disability, the scope of the examination shall include any laboratory or additional studies

that are deemed necessary, either as a result of the physical examination or pertinent information elicited from the alien's medical history or other relevant records.

(c) Additional medical screening and testing for examinations performed outside the United States.

(1) HHS/CDC may require additional medical screening and testing for medical examinations performed outside the United States for diseases specified in §§ 34.2(b)(2) and 34.2(b)(3) by applying the risk-based medical and epidemiologic factors in paragraph (d)(2) of this section.

(2) Such examinations shall be conducted in a defined population in a geographic region or area outside the United States as determined by HHS/CDC.

(3) Additional medical screening and testing shall include a medical interview, physical examination, laboratory testing, radiologic exam, or other diagnostic procedure, as determined by HHS/CDC.

(4) Additional medical screening and testing will continue until HHS/CDC determines such screening and testing is no longer warranted based on factors such as the following: Results of disease outbreak investigations and response efforts; effectiveness of containment and control measures; and the

status of an applicable determination of public health emergency of international concern declared by the Director General of the WHO.

(5) HHS/CDC will directly provide medical examiners information pertaining to all applicable additional requirements for medical screening and testing, and will post these at the following Internet addresses: <http://www.cdc.gov/ncidod/dq/technica.htm> and <http://www.globalhealth.gov>

(d) Risk-based approach. (1) HHS/CDC will use the medical and epidemiological factors listed in paragraph (d) (2) of this section to determine the following:

(i) Whether a disease as specified in § 34.2(b) (3) (ii) is a communicable disease of public health significance;

(ii) Which diseases in § 34.2(b) (2) and (3) merit additional screening and testing, and the geographic area in which HHS/CDC will require this screening.

(2) Medical and epidemiological factors include the following:

(i) The seriousness of the disease's public health impact;

(ii) Whether the emergence of the disease was unusual or unexpected;

(iii) The risk of the spread of the disease in the United States;

(iv) The transmissibility and virulence of the disease; (v) The impact of the disease at the geographic location of medical screening; and

(vi) Other specific pathogenic factors that would bear on a disease's ability to threaten the health security of the United States.

(e) Persons subject to requirement for chest radiograph examination and serologic testing. (1) As provided in paragraph (e)(2) of this section, a chest radiograph examination and serologic testing for syphilis shall be required as part of the examination of the following:

(i) Applicants for immigrant visas;

(ii) Students, exchange visitors, and other applicants for non-immigrant visas required by a U.S. consular authority to have a medical examination;

(iii) Applicants outside the United States who apply for refugee status;

(iv) Applicants in the United States who apply for adjustment of their status under the immigration statute and regulations.

(v) Applicants required by DHS to have a medical examination in connection with determination of their admissibility into the United States.

(2) Chest radiograph examination and serologic testing. Except as provided in paragraph (e) (2) (iv) of this section, applicants described in paragraph (e) (1) of this section shall be required to have the following:

(i) For applicants 15 years of age and older, a chest radiograph examination;

(ii) For applicants under 15 years of age, a chest radiograph examination if the applicant has symptoms of tuberculosis, a history of tuberculosis, or evidence of possible exposure to a transmissible tuberculosis case in a household or other enclosed environment for a prolonged period;

(iii) For applicants 15 years of age and older, serologic testing for syphilis and other communicable diseases of public health significance as determined by the Director through technical instructions.

(iv) Exceptions. Serologic testing for syphilis shall not be required if the alien is under the age of 15, unless there is reason to suspect infection with syphilis. An alien, regardless of age, in the United States, who applies for adjustment of status to lawful permanent resident, shall not be required to have a chest radiograph examination unless their tuberculin skin

test, or an equivalent test for showing an immune response to Mycobacterium tuberculosis antigens, is positive. HHS/CDC may authorize exceptions to the requirement for a tuberculin skin test, an equivalent test for showing an immune response to Mycobacterium tuberculosis antigens, or chest radiograph examination for good cause, upon application approved by the Director.

(3) Immune response to Mycobacterium tuberculosis antigens. (i) All aliens 2 years of age or older in the United States who apply for adjustment of status to permanent residents, under the immigration laws and regulations, or other aliens in the United States who are required by DHS to have a medical examination in connection with a determination of their admissibility, shall be required to have a tuberculin skin test or an equivalent test for showing an immune response to Mycobacterium tuberculosis antigens. Exceptions to this requirement may be authorized for good cause upon application approved by the Director. In the event of a positive test of immune response, a chest radiograph examination shall be required. If the chest radiograph is consistent with tuberculosis, the alien shall be referred to the local health authority for evaluation. Evidence of this evaluation shall be provided to the civil surgeon before a medical notification may be issued.

(ii) Aliens in the United States less than 2 years of age shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to Mycobacterium tuberculosis antigens, if there is evidence of contact with a person known to have tuberculosis or other reason to suspect tuberculosis. In the event of a positive test of immune response, a chest radiograph examination shall be required. If the chest radiograph is consistent with tuberculosis, the alien shall be referred to the local health authority for evaluation. Evidence of this evaluation shall be provided to the civil surgeon before a medical notification may be issued.

(iii) Aliens outside the United States required to have a medical examination shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to Mycobacterium tuberculosis antigens, and, if indicated, a chest radiograph.

(iv) Aliens outside the United States required to have a medical examination shall be required to have a tuberculin skin test, or an equivalent, appropriate test to show an immune response to Mycobacterium tuberculosis antigens, and a chest radiograph, regardless of age, if he/she has symptoms of tuberculosis, a history of tuberculosis, or evidence of possible exposure to a transmissible tuberculosis case in a household or other enclosed

environment for a prolonged period, as determined by the Director.

(4) Additional testing requirements. All applicants may be required to undergo additional testing for tuberculosis based on the medical evaluation.

(5) How and where performed. All chest radiograph images used in medical examinations performed under the regulations to this part shall be large enough to encompass the entire chest.

(6) Chest x-ray, laboratory, and treatment reports. The chest radiograph reading and serologic test results for syphilis shall be included in the medical notification. When the medical examiner's conclusions are based on a study of more than one chest x-ray image, the medical notification shall include at least a summary statement of findings of the earlier images, followed by a complete reading of the last image, and dates and details of any laboratory tests and treatment for tuberculosis.

(f) Procedure for transmitting records. For aliens issued immigrant visas, the medical notification and chest radiograph images, if any, shall be placed in a separate envelope, which shall be sealed. When more than one chest radiograph image is used as a basis for the examiner's conclusions, all images shall be included. Records may be transmitted by other means, as approved by the Director.

(g) Failure to present records. When a determination of admissibility is to be made at the U.S. port of entry, a medical hold document shall be issued pending completion of any necessary examination procedures. A medical hold document may be issued for aliens who:

(1) Are not in possession of a valid medical notification, if required;

(2) Have a medical notification which is incomplete;

(3) Have a medical notification which is not written in English;

(4) Are suspected to have an inadmissible medical condition.

(h) The Secretary of Homeland Security, after consultation with the Secretary of State and the Secretary of Health and Human Services, may in emergency circumstances permit the medical examination of refugees to be completed in the United States.

(i) All medical examinations shall be carried out in accordance with such technical instructions for physicians conducting the medical examination of aliens as may be issued by the Director. Copies of such technical instructions are available upon request to the Director, Division of Global Migration and Quarantine, Mailstop E03, HHS/CDC, Atlanta GA 30333.

**§ 34.4 Medical notifications.**

(a) Medical examiners shall issue medical notifications of their findings of the presence or absence of Class A or Class B medical conditions. The presence of such condition must have been clearly established.

(b) Class A medical notifications. (1) The medical examiner shall report his/her findings to the consular officer or DHS by Class A medical notification which lists the specific condition for which the alien may be inadmissible, if an alien is found to have:

- (i) A communicable disease of public health significance;
- (ii) A lack of documentation, or no waiver, for an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, of having received vaccination against vaccine-preventable diseases which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which HHS/CDC determines, by applying criteria published in the Federal Register, there is a public health need at the time of immigration or adjustment of status. Provided however, that a Class A medical notification

shall in no case be issued for an adopted child who is 10 years of age or younger if, prior to the admission of the child, an adoptive parent or prospective adoptive parent of the child, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that, within 30 days of the child's admission, or at the earliest time that is medically appropriate, the child will receive the vaccinations identified in the requirement;

(iii) (A) A current 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 alien or others; or

(B) A history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior;

(iv) Drug abuse or drug addiction. Provided, however, that a Class A medical notification of a physical or mental disorder, and behavior associated with that disorder that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others, shall in no case be issued with respect to an alien having only mental shortcomings due to ignorance, or suffering

only from a condition attributable to remediable physical causes or of a temporary nature, caused by a toxin, medically prescribed drug, or disease.

(2) The medical notification shall state the nature and extent of the abnormality; the degree to which the alien is incapable of normal physical activity; and the extent to which the condition is remediable. The medical examiner shall indicate the likelihood, that because of the condition, the applicant will require extensive medical care or institutionalization.

(c) Class B medical notifications. (1) If an alien is found to have a physical or mental abnormality, disease, or disability serious in degree or permanent in nature amounting to a substantial departure from normal well-being, the medical examiner shall report his/her findings to the consular or DHS officer by Class B medical notification which lists the specific conditions found by the medical examiner. Provided, however, that a Class B medical notification shall in no case be issued with respect to an alien having only mental shortcomings due to ignorance, or suffering only from a condition attributable to remediable physical causes or of a temporary nature, caused by a toxin, medically prescribed drug, or disease.

(2) The medical notification shall state the nature and extent of the abnormality, the degree to which the alien is

incapable of normal physical activity, and the extent to which the condition is remediable. The medical examiner shall indicate the likelihood, that because of the condition, the applicant will require extensive medical care or institutionalization.

(d) Other medical notifications. If as a result of the medical examination, the medical examiner does not find a Class A or Class B condition in an alien, the medical examiner shall so indicate on the medical notification form and shall report his findings to the consular or DHS officer.

#### **§ 34.5 Postponement of medical examination.**

Whenever, upon an examination, the medical examiner is unable to determine the physical or mental condition of an alien, completion of the medical examination shall be postponed for such observation and further examination of the alien as may be reasonably necessary to determine his/her physical or mental condition. The examination shall be postponed for aliens who have an acute infectious disease until the condition is resolved. The alien shall be referred for medical care as necessary.

#### **§ 34.6 Applicability of Foreign Quarantine Regulations.**

Aliens arriving at a port of the United States shall be subject to the applicable provisions of 42 CFR part 71, Foreign Quarantine, with respect to examination and quarantine measures.

**§ 34.7 Medical and other care; death.**

(a) An alien detained by or in the custody of DHS may be provided medical, surgical, psychiatric, or dental care by HHS through interagency agreements under which DHS shall reimburse HHS. Aliens found to be in need of emergency care in the course of medical examination shall be treated to the extent deemed practical by the attending physician and if considered to be in need of further care, may be referred to DHS along with the physician's recommendations concerning such further care.

(b) In case of the death of an alien, the body shall be delivered to the consular or immigration authority concerned. If such death occurs in the United States, or in a territory or possession thereof, public burial shall be provided upon request of DHS and subject to its agreement to pay the burial expenses. Autopsies shall not be performed unless approved by DHS.

**§ 34.8 Reexamination; convening of review boards; expert witnesses; reports.**

(a) The Director shall convene a board of medical officers to reexamine an alien:

(1) Upon the request of DHS for a reexamination by such a board;  
or

(2) Upon an appeal to DHS by an alien who, having received a medical examination in connection with the determination of admissibility to the United States (including examination on arrival and adjustment of status as provided in the immigration laws and regulations) has been certified for a Class A condition.

(b) The board shall reexamine an alien certified as:

(1) Having a communicable disease of public health significance;

(2) Lacking documentation of having received vaccination against "vaccine-preventable diseases" for an alien who seeks admission as an immigrant, or who seeks adjustment of status to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenza type B and hepatitis B, and any other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which HHS/CDC determines, by applying criteria published in the Federal Register, there is a public health need at the time of immigration or adjustment of status. Provided, however, that in no case shall a Class A medical notification be issued for an adopted child who is 10 years of age or younger if, prior to the admission of the child, an adoptive or prospective adoptive

parent, who has sponsored the child for admission as an immediate relative, has executed an affidavit stating that the parent is aware of the vaccination requirement and will ensure that the child will be vaccinated within 30 days of the child's admission, or at the earliest time that is medically appropriate.

(3) (i) Having a current 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 alien or others; or

(ii) Having a history of a physical or mental disorder and behavior associated with the disorder, which behavior has posed a threat to the property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior; or

(iii) Having drug abuse or drug addiction;

(c) The board shall consist of the following:

(1) In circumstances covered by paragraph (b) (1) of this section, the board shall consist of at least one medical officer who is experienced in the diagnosis and treatment of the communicable disease for which the medical notification has been made;

(2) In circumstances covered by paragraph (b) (2) of this section, the board shall consist of at least one medical officer

who is experienced in the diagnosis and treatment of the vaccine-preventable disease for which the medical notification has been made;

(3) In circumstances covered by paragraph (b) (3) of this section, the board shall consist of at least one medical officer who is experienced in the diagnosis and treatment of the physical or mental disorder, or substance-related disorder for which medical notification has been made.

(d) The decision of the majority of the board shall prevail, provided that at least two medical officers concur in the judgment of the board.

(e) Reexamination shall include:

(1) Review of all records submitted by the alien, other witnesses, or the board;

(2) Use of any laboratory or additional studies which are deemed clinically necessary as a result of the physical examination or pertinent information elicited from the alien's medical history;

(3) Consideration of statements regarding the alien's physical or mental condition made by a physician after his/her examination of the alien; and

(4) A physical or psychiatric examination of the alien performed by the board, at the board's discretion;

(f) An alien who is to be reexamined shall be notified of the reexamination not less than 5 days prior thereto.

(g) The alien, at his/her own cost and expense, may introduce as witnesses before the board such physicians or medical experts as the board may in its discretion permit; provided that the alien shall be permitted to introduce at least one expert medical witness. If any witnesses offered are not permitted by the board to testify (either orally or through written testimony), the record of the proceedings shall show the reason for the denial of permission.

(h) Witnesses before the board shall be given a reasonable opportunity to review the medical notification and other records involved in the reexamination and to present all relevant and material evidence orally or in writing until such time as the reexamination is declared by the board to be closed. During the course of the reexamination the alien's attorney or representative shall be permitted to question the alien and he/she, or the alien, shall be permitted to question any witnesses offered in the alien's behalf or any witnesses called by the board. If the alien does not have an attorney or representative, the board shall assist the alien in the presentation of his/her case to the end that all of the material and relevant facts may be considered.

(i) Any proceedings under this section may, at the board's discretion, be conducted based on the written record, including through written questions and testimony.

(j) The findings and conclusions of the board shall be based on its medical examination of the alien, if any, and on the evidence presented and made a part of the record of its proceedings.

(k) The board shall report its findings and conclusions to DHS, and shall also give prompt notice thereof to the alien if his/her reexamination has been based on his/her appeal. The board's report to DHS shall specifically affirm, modify, or reject the findings and conclusions of prior examining medical officers.

(l) The board shall issue its medical notification in accordance with the applicable provisions of this part if it finds that an alien it has reexamined has a Class A or Class B condition.

(m) If the board finds that an alien it has reexamined does not have a Class A or Class B condition, it shall issue its medical notification in accordance with the applicable provisions of this part.

(n) After submission of its report, the board shall not be

reconvened, nor shall a new board be convened, in connection with the same application for admission or for adjustment of status, except upon the express authorization of the Director.

Dated: January 12, 2016.

**Sylvia M. Burwell,**  
*Secretary.*

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