



Billing Code: 4163-18-P

**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:** Notice of proposed rulemaking.

**SUMMARY:** The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is issuing this Notice of Proposed Rulemaking (NPRM) to amend its regulations governing medical examinations that aliens must undergo before they may be admitted to the United States. Specifically, HHS/CDC proposes to: 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:** Written comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by the Regulatory Information Number (RIN) 0920-AA28 or the Docket Number CDC-2015-0045 in the heading of this document by any of the following methods:

- Federal eRulemaking Portal:

<http://www.regulations.gov>. Follow the instructions for submitting comments.

- Mail: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS E-03, Atlanta, GA 30333, ATTN: Part 34.

- Hand Delivery/Courier: Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS E-03, Atlanta, GA 30333, ATTN: Part 34.

- Viewing Comments: Comments may be viewed at [www.regulations.gov](http://www.regulations.gov), Docket Number CDC-2015-0045.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to <http://www.regulations.gov> and refer to Docket Number CDC-2015-0045. Comments will be available for public inspection from Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 1600 Clifton Road, N.E., Atlanta, Georgia 30333. Please call ahead to 1-866-694-4867, and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit.

**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 30333; telephone 1-404-498-1600.

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

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**I. Public Participation.**

Interested persons are invited to participate in this  
rulemaking by submitting written views, opinions,

recommendations, and data. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure.

Specifically, HHS/CDC seeks 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. Please note when considering this question that HHS/CDC is not requesting comment on the statutory language itself as HHS/CDC does not have the authority to alter statutory language. Rather, we are 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. CDC is 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 the convening of a medical review board and reexamination of an alien by a medical review board should be revised as proposed in this regulation.

Do not include any information in your comment or supporting materials that you do not wish to be disclosed publicly.

## **II. Legal Authority**

HHS/CDC is proposing these revisions under the authority of 42 U.S.C. 252 and 8 U.S.C. 1182 and 1222.

## **III. Background**

### A. Inadmissibility and the Medical Examination

Under section 212(a)(1) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(1)), any alien who is determined to have a communicable disease of public health significance is inadmissible to the United States. As a result of this statute, aliens outside of the United States who have a communicable disease of public health significance are ineligible to receive a visa for admission into the United States, absent the grant of a waiver. Aliens within the United States who have a communicable disease of public health significance are also ineligible to adjust their status to that of a lawful permanent resident, absent the grant of a waiver.

In addition to other potential grounds of inadmissibility, an alien is inadmissible if he/she is determined: (1) To have a communicable disease of public health significance (as currently defined by regulations); (2) to pose, or has posed, a threat to the property, safety, or welfare of the alien or others; (3) to have had a history of behavior, which has posed a threat to the property, safety, or welfare of the alien or others and which is likely to recur or lead to other harmful behavior; or (4) to be a drug abuser or addict.

At present, except for certain adopted children 10 years of age or younger, HHS/CDC requires any alien seeking admission as an immigrant or seeking adjustment of status to that of a lawful permanent resident, to present documentation of vaccination against all vaccine-preventable diseases explicitly listed in section 212(a)(1)(A)(ii) of the INA (mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenzae type B, hepatitis B), and for all other vaccinations recommended by the Advisory Committee for Immunization Practices (ACIP) for which a public health need exists at the time of immigration or adjustment of status.



To allow HHS/CDC to adapt vaccination requirements for U.S. immigrants based on public health needs, on April 8, 2009, HHS/CDC published a notice in the Federal Register (74 FR 15986) seeking public comment on 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. The proposed criteria are as follows: the vaccine must be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population, and at least one of the following: (i) the vaccine must protect against a disease that has the potential to cause an outbreak; or (ii) the vaccine must protect against a disease that has been eliminated in the United States or is in the process for elimination in the United States. HHS/CDC received public comment on these criteria and after review and consideration, published a final notice on November 13, 2009, adopting the proposed criteria (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 list of the ACIP vaccine recommendations for the U.S. general public can be found at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>, and the list of HHS/CDC required vaccines for immigration purposes can be found at <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/panel/vaccination-panel-technical-instructions.html#tbl1>. As more vaccines become available, HHS/CDC will continue to apply these criteria to respond to the ACIP vaccination recommendations.

Any changes to the list of required vaccines, which result from an application of these criteria, will be reflected in HHS/CDC's Technical Instructions, available to the public at <http://www.cdc.gov/immigrantrefugeehealth/exams/ti/index.html>. While HHS/CDC is not seeking additional comment on these previously published vaccination criteria at this time, we are requesting comment on incorporating the reference to these criteria in this regulation. 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.

The Secretary of Health and Human Services (HHS) is authorized to promulgate regulations establishing the requirements for the medical examination of aliens by sections 212(a) (1) and 232 of the INA and section 325 of the Public Health Service Act (42 U.S. C. 252). The regulations, administered by HHS/CDC, are promulgated at 42 CFR part 34. Under current 42 CFR part 34, an alien seeking permanent residence prior to arrival into the U.S. or through an adjustment of status while in the U.S., must undergo a medical examination to determine whether the alien is inadmissible on medical grounds.

HHS/CDC issues Technical Instructions that provide the technical consultation and guidance to panel physicians and civil surgeons who conduct the medical examinations of aliens. Panel physicians, designated by the U.S. Department of State (DOS), perform medical examinations on those aliens living outside the United States who are seeking to immigrate to the United States. Civil surgeons, designated by the U.S. Citizenship and Immigration Services (USCIS) within the U.S. Department of Homeland Security (DHS), perform medical examinations for aliens who are already present in the United States and are seeking adjustment of status. The CDC Technical Instructions for Medical

Examination of Aliens, including the most current updates that panel physicians and civil surgeons must follow in accordance with these regulations, are available to the public on the CDC website, located at the following Internet address:

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

B. Applicability of part 34:

The provisions in 42 CFR part 34 apply to the medical examination of 1) aliens outside the United States who are applying for a visa at an embassy or consulate of the United States; 2) aliens arriving in the United States; 3) aliens required by DHS to have a medical examination in connection with determination of their admissibility into the United States; and 4) aliens who apply for adjustment of their immigration status to that of lawful permanent resident. While 42 CFR part 34 can apply to individuals who wish to come to the United States to visit, such as leisure or business travelers, a medical examination is not routinely required as a condition for issuance of non-immigrant visas or entry into the United States.

Annually, DHS admits more than 1 million aliens to reside permanently in this country (24). Foreign citizens who wish to live permanently in the United States must comply with U.S. immigration law and specific procedures for applying for an immigrant visa or adjustment of status. These applicants are also subject to the medical grounds of inadmissibility. The four main immigrant visa classifications are: 1) Immediate Relatives, that is, the spouse, child (unmarried and under 21 years of age) or parent of a U.S. citizen (a citizen must be at least 21 years old to file a petition for a parent); 2) Family-Based immigrants (adult sons or daughters of citizens, the siblings of citizens who are at least 21 years old, and the spouse, child, or adult sons or daughters of lawful permanent residents); 3) Employment-Based immigrants; and 4) Diversity immigrants who obtain by lottery the ability to seek an immigrant visa.

Refugees and asylees may also apply to adjust to permanent resident status from inside the United States. INA section 209; 8 U.S.C. 1159. Section 101(a)(42)(A) of the INA generally defines refugees and asylees as persons who cannot return to their country because of persecution or the well-founded fear of persecution based on race,

religion, nationality, membership in a particular social group, or political opinion. A refugee applicant is preliminarily approved for refugee status overseas, but is admitted as a refugee upon admission to the United States at a port of entry. An asylee applicant is approved for asylum from within the United States and is not required to undergo a medical examination as part of the application process until he/she seeks adjustment of status. See INA 208 and 8 CFR Part 208. A refugee is subject to the medical grounds of inadmissibility and the medical examination requirements. A refugee is not subject to the vaccination requirements until he/she seeks adjustment of status. See INA section 207; 8 U.S.C. 1157; 8 CFR part 207.

An additional immigration category under the INA is Temporary Protected Status (TPS). This applies to persons who are in the United States lawfully, though temporarily, as a result of ongoing armed conflict, natural disasters, or certain other extraordinary and temporary conditions, and whose countries have been designated as TPS countries under INA section 244; 8 U.S.C. 1255a; 8 CFR part 244. TPS applicants are also subject to the medical grounds of inadmissibility.

C. Legislative and Regulatory History of part 34

Beginning in 1952, the language of the 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, Public Law 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. 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), 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, that removed HIV infection and testing for HIV infection from part 34 regulations. 74 FR 31798 and 73 FR 56547.

Through today's NPRM, HHS/CDC is soliciting public comment on the definition of communicable disease of public health significance and the revised scope of medical examination which were initially promulgated as an interim final rule in 2008. Specifically, in addition to the previously updated language, HHS/CDC proposes to further revise the definition of communicable disease of public health significance by removing these three uncommon health conditions: chancroid; granuloma inguinale; and

lymphogranuloma venereum. This definition is now proposed to include 1) quarantinable diseases designated by Presidential Executive Order; 2) a communicable disease that may pose a public health emergency of international concern in accordance with the IHR of 2005; and 3) gonorrhea, infectious Hansen's disease, infectious syphilis, and active tuberculosis.

HHS/CDC is not proposing to remove active tuberculosis from the definition of a communicable disease of public health significance. At this time, HHS/CDC is not proposing to remove infectious leprosy, gonorrhea, or syphilis from the definition but is proposing to replace the term "infectious leprosy" with "infectious Hansen's disease" and to modify "syphilis, infectious stage" to simply "syphilis, infectious" to reflect modern terminology. HHS/CDC will accept public comment on whether these three diseases should remain or be removed from the definition of communicable disease of public health significance.

HHS/CDC's rationale for maintaining these three diseases is that continuing to screen for and treat these diseases, when identified in aliens, provides a public health benefit to the United States as well as a personal 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 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.

#### **IV. Rationale for Proposed Regulatory Action**

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 NPRM, HHS/CDC proposes to update 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 proposing to update part 34 so that the text accurately

reflects the statutory and administrative changes that have occurred within the Federal Government regarding agencies and/or departments responsible for this process. These updates 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 analysis of the proposed changes for which HHS/CDC is seeking public comment:

A. 34.1 Applicability

HHS/CDC is proposing to replace 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.

B. Section 34.2 Definitions

Current section 34.2 entitled "Definitions" provides information regarding the intent of HHS/CDC regarding certain terms that are used in the regulation. While HHS/CDC is not proposing to revise all of the current terms and definitions, such as medical examiner, we welcome

comment on the use of these terms and its definitions.

HHS/CDC is proposing to revise the definitions section as specifically described below.

HHS/CDC proposes to revise 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. To help guide the reader, we have provided a chart to indicate which text is proposed to change and is therefore subject to comments from the public.

| Current Definitions and Corresponding Proposed Changes in Definitions within the NPRM  |   |
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| Definitions in 42 CFR part 34  | Corresponding, New, or Updated Definition within NPRM   |
| <u>CDC</u> . Centers for Disease Control, Public Health Services, U.S. Department of Health and Human Services.  | <u>CDC</u> . Centers for Disease Control and Prevention, U.S. Department of Health and Human Services.  |
| <u>Communicable disease of public health significance</u> . Any of the following diseases:<br>(1) Chancroid.<br><br>(2) Communicable diseases as listed in a presidential Executive Order, as provided under | <u>Communicable disease of public health significance</u> . Any of the following diseases:<br>(1) Communicable diseases as listed in a Presidential Executive Order, as provided under Section 361(b) of the Public Health Service Act. |

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> .

(3) Communicable diseases that may pose a public health emergency of international concern if it meets one or more of the factors listed in in § 34.3(d) and for which the CDC Director has determined (A) a threat exists for importation into the United States, and (B) 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 revised International Health Regulations ([http://www.who.int/csr/ih\\_r/en/](http://www.who.int/csr/ih_r/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

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 in §34.3(d) and for which the CDC Director has determined (A) a threat exists for importation into the United States, and (B) 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 revised International Health Regulations ([http://www.who.int/csr/ih\\_r/en/](http://www.who.int/csr/ih_r/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,

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| <p>of international concern, or,</p> <p>(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.</p> <p>(4) Gonorrhea.</p> <p>(5) Granuloma inguinale.</p> <p>(6) Leprosy, infectious.</p> <p>(7) Lymphogranuloma venereum.</p> <p>(8) Syphilis, infectious stage.</p> <p>(9) Tuberculosis, active.</p> | <p>(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.</p> <p>(3) Gonorrhea.</p> <p>(4) Hansen's disease, infectious.</p> <p>(5) Syphilis, infectious.</p> <p>(6) Tuberculosis, active.</p> |
| <p><u>Civil surgeon.</u> A physician, with not less than 4 years' professional experience, selected by the District Director of INS 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 the INS to have a medical examination.</p>   | <p><u>Civil surgeon.</u> A physician selected 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.</p>   |
| <p><u>Class A medical notification.</u></p> <p>(1) A communicable disease of public health significance;</p> <p>(2) (i) A physical or mental disorder and behavior associated with the disorder</p>   | <p><u>Class A medical notification.</u></p> <p>(1) A communicable disease of public health significance;</p> <p>(2) A failure to present documentation of having received vaccination against</p>  |

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| <p>that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others;</p> <p>(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</p> <p>(3) Drug abuse or addiction.</p> | <p>“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, <u>Haemophilus influenza</u> type B, and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices (ACIP) for which HHS/CDC determines there is a public health need at the time of immigration or adjustment of status.</p> <p>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.</p> <p>(3) (i) A current disorder and behavior that may pose, or has posed, a threat to the</p> |
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|   | <p>property, safety, or welfare of the alien or others;</p> <p>(ii) A history of 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</p> <p>(4) Drug abuse or addiction.</p>   |
| <p><u>Class B medical notification.</u> Medical notification of a physical or mental health condition, disease, or disability serious in degree or permanent in nature amounting to a substantial departure from normal well-being.</p> | <p>Class B medical notification. Medical notification of a physical or mental health condition, disease, or disability serious in degree or permanent in nature.</p>  |
|   | <p><u>DHS.</u> U.S. Department of Homeland Security.</p>  |
| <p><u>Director.</u> The Director of the Centers for Disease Control</p>   | <p><u>Director.</u> The Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary.</p>   |
| <p><u>Drug abuse.</u> The non-medical use of a substance listed in section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802) which has not necessarily resulted in physical or psychological dependence.</p>             | <p><u>Drug abuse.</u> Current substance use disorder or substance-induced disorder, mild, as defined in the current edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM) published by the American Psychiatric Association, or in another authoritative source as approved by the Director, of a substance listed in Section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802).</p> |

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| <p><u>Drug addiction.</u> The non-medical use of a substance listed in section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802) which has resulted in physical or psychological dependence.</p>   | <p><u>Drug addiction.</u> Current substance use disorder or substance-induced disorder, moderate or severe as defined in the current edition of the Diagnostic and Statistical Manual for Mental Disorders (DSM) published by the American Psychiatric Association, or in another authoritative source as approved by the Director, of a substance listed in Section 202 of the Controlled Substances Act, as amended (21 U.S.C. 802).</p> |
|   | <p><u>HHS.</u> U.S. Department of Health and Human Services</p>  |
| <p><u>INS.</u> Immigration and Naturalization Service, U.S. Department of Justice</p>   | <p>Definition Removed.</p>   |
| <p><u>Medical examiner.</u> A panel physician, civil surgeon, or other physician designated by the Director to perform medical examination of aliens.</p>   | <p><u>No change.</u></p>   |
| <p><u>Medical hold document.</u> A document issued to the INS by a quarantine inspector of the Public Health Service at a port of entry, which defers the inspection for admission until the cause of the medical hold is resolved.</p>   | <p><u>Medical hold document.</u> A document issued to DHS by a quarantine officer of HHS/CDC at a port of entry, which defers the inspection for admission until the cause of the medical hold is resolved.</p>  |
| <p><u>Medical notification.</u> A document issued to a consular authority or the INS by a medical examiner, certifying the presence or absence of:<br/> (1) A communicable disease of public health significance<br/> (2) (i) A physical or mental disorder and behavior associated with the disorder that may pose, or has posed, a threat to the property, safety, or welfare of the alien or</p> | <p><u>Medical notification.</u> A document issued to a consular authority or DHS by a medical examiner, certifying the presence or absence of:<br/> (1) A communicable disease of public health significance<br/> (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</p>  |

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| <p>others;</p> <p>(ii) A history of a physical or mental 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;</p> <p>(3) Drug abuse or addiction; or</p> <p>(4) Any other physical abnormality, disease, or disability serious in degree or permanent in nature amounting to a substantial departure from normal well-being.</p> | <p>to one lawfully admitted for permanent residence, which shall include at least the following diseases: mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, <u>Haemophilus influenza</u> type B, and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices (ACIP) for which HHS/CDC determines there is a public health need at the time of immigration or adjustment of status.</p> <p>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.</p> <p>(3) (i) A behavior that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others;</p> <p>(ii) A history of a behavior has posed a threat to the</p> |
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|   | <p>property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior;</p> <p>(4) Drug abuse or addiction;</p> <p>(5) Any other physical or mental condition, disease or disability serious in degree or permanent in nature..</p>                                  |
| <p><u>Medical officer.</u> A physician of the Public Health Service Commissioned Corps assigned by the Director to conduct physical and mental examinations of aliens.</p>  | <p><u>Medical officer.</u> A physician assigned by the Director to conduct physical and mental examinations of aliens on behalf of HHS/CDC.</p>  |
| <p><u>Mental disorder.</u> A currently accepted psychiatric diagnosis, as defined by the Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, or by other authoritative sources.</p>                        | <p><u>Mental disorder.</u> A currently accepted psychiatric diagnosis, as defined by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association, or by other authoritative sources as approved by the Director.</p>                        |
| <p><u>Panel physician.</u> A physician selected by a United States embassy or consulate to conduct medical examinations of aliens applying for visas.</p>   | <p>No change.</p>  |
| <p><u>Physical disorder.</u> A currently accepted medical diagnosis, as defined by the Manual of the International Classification of Diseases, Injuries, and Causes of Death published by the World Health Organization, or by other authoritative sources.</p> | <p><u>Physical disorder.</u> A currently accepted medical diagnosis, as defined by the most recent version of the Manual of the International Classification of Diseases (ICD), Injuries, and Causes of Death published by the World Health Organization, or by other authoritative sources as approved by the Director.</p> |

Section 34.2(a) CDC

We are proposing to update the definition of CDC 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 are removing "Public Health Services" from the definition.

Section 34.2(b) Communicable disease of public health significance

This provision 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. HHS/CDC is proposing to remove 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).

HHS/CDC uses epidemiological principles and current medical practice to assess and revise the list of diseases defined as a communicable disease of public health significance. Guided by such principles and practice, HHS/CDC believes that these three sexually transmitted

infections no longer pose such a significant threat to the general U.S. population, that aliens with these infections should not be denied admission to the United States. The three bacterial infections (chancroid, granuloma inguinale and lymphogranuloma venereum), all primarily transmitted through sexual contact, have never been common in the United States and over the past two decades have been observed to be increasingly rare throughout the world (6, 8). Of the three bacterial infections, only laboratory-diagnosed cases of chancroid are reportable conditions in the United States, and since 2005 fewer than 30 chancroid cases annually were reported to CDC from the U.S. states and territories (6-22).

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 HHS/CDC by clinicians and public health departments. 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 are 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). Additionally, cases of lymphogranuloma venereum are increasingly rare among women. Although sporadic small outbreaks of lymphogranuloma venereum have occurred over the past 10 years, these have been almost exclusively among men who have sex with men, with disease generally manifested as severe proctitis (inflammation of the anus or rectum) (18-20).

Internationally, most countries do not track any of the three infections; however, the few publications and records available suggest case rates have declined worldwide over the past 50 years. Declining rates of these conditions are likely due to a variety of factors. Improved living conditions, better sanitation (e.g., availability of soap and water), condom use, and educational efforts are all believed to be important factors (6, 21-23) contributing to the decline in the incidence of these infections. Improved recognition by physicians and treatment based on clinical presentation of sexually transmitted infections, coupled with treatment of sexual partners, also appears to be important in their decline. Increased antibiotic usage for treatment of other unrelated conditions may have contributed to the declining incidence of these infections.

Additionally, HIV prevention strategies such as male circumcision may be playing a role, although definitive studies of this effect are still pending.

Given the low burden of these three infections globally, the potential introduction of additional cases into the United States by aliens is likely to have a negligible impact on the U.S. population for several reasons. As mentioned, these primarily tropical infections can be prevented through improved personal hygiene (11); protected sex (use of a condom); and treatment of sexual partners. Such infections can be effectively treated and cured with relatively uncomplicated courses of antibiotic therapy. None of the three infections is associated with excess mortality (premature death); and most cases do not lead to serious long term consequences, disability or excessive medical costs.

After careful consideration of epidemiological principles and current medical practice, scientific evidence indicates that chancroid, granuloma inguinale, and lymphogranuloma venereum do not represent a significant risk for introduction, transmission, and spread from foreign countries to the United States population. Therefore, HHS/CDC proposes to remove these three diseases from the specific list of communicable disease of public health



significance and is seeking public comment on this proposal.

#### Section 34.2 (c) Civil Surgeon

Civil Surgeon is currently defined as a "physician, with not less than 4 years professional experience, selected by the District Director of INS 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 the INS to have a medical examination." HHS/CDC is proposing to remove 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 DHS regulations in 8 CFR Part 232. HHS/CDC also proposes to remove "with not less than 4 years' professional experience" from the definition of civil surgeon. Through complimentary regulations promulgated by DHS at 8 CFR 232, the requirement of 4 years' professional experience for civil surgeons will remain in effect. We are proposing this change because DHS is responsible for designating civil surgeons and should therefore have the discretion to determine the necessary prerequisites for that position. Thus, CDC is simply proposing to remove a redundancy found

in its regulations and is not affecting a substantive change in policy. HHS/CDC will continue to consult with DHS/USCIS as needed, regarding recommendations for civil surgeon requirements. Therefore, HHS/CDC is proposing civil surgeon to mean 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 proposing to amend 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. HHS/CDC is proposing to update part 34 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 is a reflection of updated statutory language. As noted

above, HHS/CDC is not authorized to change statutory requirements; thus, CDC is not requesting comment on the statutory language, but on the advisability of incorporating statutory language into regulations. Additionally, CDC seeks to incorporate and is requesting comment on its understanding that the statutory requirement for proof of vaccination in regard to ACIP-recommended vaccines only applies to those vaccines that are appropriate in an immigration context and for which a public health need exists at the time of immigration or adjustment of status.

The proposed 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 will not change current practices, but is a reflection of updated statutory language. Again, because HHS/CDC is not authorized to change statutory requirements, HHS/CDC is not requesting comment on the statutory language, but will accept comment on the advisability of incorporating statutory language into regulations. HHS/CDC believes that the inclusion of statutory language promotes greater transparency and a better understanding of immigration requirements. For further information, please visit:

<http://www.uscis.gov/ilink/docView/SLB/HTML/SLB/0-0-0-1/0-0-0-29/0-0-0-2006.html>.

#### Section 34.2(f) Director

We are proposing to update the definition of Director to reflect the current official title of the CDC Director, as well as his/her delegation authorities. Therefore, the definition of Director is proposed as: the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary.

#### Section 34.2 (g) DHS

We are proposing to add 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. The definition of DHS is proposed as: U.S. Department of Homeland Security.

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

HHS/CDC is proposing to revise the definitions of drug abuse and drug addiction by aligning with the definitions of "substance use disorders" and "substance-induced disorders," with the definitions provided by the Diagnostic and Statistical Manual for Mental Disorders (DSM) published by the American Psychiatric Association (25). HHS/CDC is taking this approach because the DSM is the medical standard for the diagnosis of mental disorders and substance-related disorders. The DSM provides current diagnostic criteria based on the latest available evidence. As such, HHS/CDC is proposing drug abuse and drug addiction to mean "current substance use disorders or substance-induced disorders" as defined in the current edition of the DSM, or in another authoritative source as approved by the Director, of a substance listed in Section

202 of the Controlled Substances Act, as amended (21 U.S.C. 802). These proposed updated definitions are not a substantive change, as it is the current practice of HHS/CDC to use the definitions found in the DSM. In the unlikely event that another authoritative source becomes more appropriate than the DSM, HHS/CDC would issue a notice in the Federal Register, update our website, and list the source in our technical instructions. We would not pursue notice and comment rulemaking unless the reliance on a new source resulted in a substantive change in CDC operations or policy.

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

HHS/CDC is proposing to update 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." HHS/CDC is proposing these changes to reflect the current Federal agency and position names and respective responsibilities and is not seeking public comment on these non-substantive changes.

#### Section 34.2 (l) Medical Notification

The medical notification is a medical examination document issued to a consular authority or to DHS by a medical examiner following examination of an applicant for immigration for inadmissible conditions. HHS/CDC is proposing to amend 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. HHS/CDC is proposing this addition to update 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 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, is proposed to mean a medical examination document issued to a consular authority or the DHS by a medical examiner that will include 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 there is a public health need at the time of immigration or adjustment of status.”

#### Section 34.2(m) Medical officer

HHS/CDC is proposing to remove “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. Removing this requirement will best protect public health by broadening the pool of medical professionals qualified and available to provide alien examination services since there are a limited number of physicians within the Public Health Service Commissioned Corps.

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

HHS/CDC is proposing to clarify 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. HHS/CDC is proposing to add "most recent" to qualify the version of the DSM referenced in this definition and clarify the intent of CDC that such diagnoses align with current science and medical practice. HHS/CDC is also allowing for the possibility of other authoritative sources in order to rely on the most recent medical science.

HHS/CDC is proposing 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 proposing to add "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 is also allowing for the possibility of other authoritative sources in order to rely on the most recent medical science. In the event that another authoritative source is determined to be more appropriate for immigration medical examination purposes, HHS/CDC will issue updated technical instructions. Again,

these are not substantive changes to the regulation as they follow current HHS/CDC practice and protocol.

ii. Section 34.3 Scope of Examinations

Current section 34.3 entitled "Scope of Examinations" 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 Section 34.2 (b) of 42 CFR part 34. HHS/CDC is proposing to further update 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 subsection (a) (2) (i), we are also proposing to insert 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)

HHS/CDC is proposing to revise 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. HHS/CDC is proposing this change as previously described in proposed changes to 34.2 Definitions.

Specific proposed revisions to Section 34.3(e)

HHS/CDC is proposing to amend § 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. HHS/CDC has added § 34.3(e)(1)(v) "Applicants required by the DHS to have a medical examination in connection with the determination of their admissibility into the United States."

HHS/CDC is proposing 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.

HHS/CDC is proposing to amend § 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 HHS/CDC has included language to allow the Director to test for other communicable diseases of public health significance (as defined) through technical instructions.

HHS/CDC is proposing to amend § 34.3(e) (3) (i) and (ii) to reflect the scope of currently available medical tests. HHS/CDC proposes to replace "positive tuberculin reaction" with "positive test of immune response to Mycobacterium tuberculosis antigens" in § 34.3(e) (3) (i) and (ii).

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

To allow for additional testing in medically appropriate circumstances, HHS/CDC is proposing to revise § 34.3(e) (4) by removing "subject to the chest radiograph requirement, and for whom the radiograph shows an abnormality suggestive of tuberculosis disease," replacing "shall" with "may," and adding "based on medical evaluation." HHS/CDC is proposing this revision to read: "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, HHS/CDC is also proposing to amend § 34.3 (b) (2) by adding “or other relevant records” to ensure that all appropriate available medical documentation may be considered. HHS/CDC is proposing this revision to read: “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.”

HHS/CDC has included language under § 34.3(f), transmission of records, to ensure that electronic submissions may be acceptable as provided by the Director. Finally, HHS/CDC is proposing to amend § 34.3(g) (4) by replacing “excludable” with “inadmissible” in § 34.3(g) (4) to reflect modern terminology.

### iii. Section 34.4 Medical notifications

HHS/CDC proposes to revise § 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 to reference criteria established by CDC and published in Federal Register Notices to determine which vaccines recommended by the ACIP will be required for U.S. immigration. In addition, HHS/CDC is proposing to add specific language regarding the exemption of vaccination requirements for an adopted child as provided in section 212 of the INA. Again, these changes are not substantive, but reflect current practice and statutory language.

iv. Section 38.7 Medical and other care; death.

Under this section, HHS/CDC proposes to replace "INS" with "DHS" and replace "Public Health Services" with "HHS" to reflect modern agency titles and appropriate authorities relating to this provision. Although HHS/CDC is not proposing to make any substantive changes to § 38.7, we will accept public comment on updating this section to reflect modern terminology.

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

Review boards are convened by the Director to reexamine aliens at the request of DHS and upon appeal to DHS by an alien certified as having a Class A condition. HHS/CDC is

proposing changes to this section to clarify the reexamination and review board's process and improve the expediency of the process. The proposed changes 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 will be 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, HHS/CDC is proposing to add failure to present documented proof of having been vaccinated against vaccine preventable diseases as a basis for reexamination by the review board and add clarifying language that the reexamination may be conducted, at the board's discretion, based on the written record.

By removing the requirement that one medical officer must be a board-certified psychiatrist, HHS/CDC will be able to more easily and efficiently comprise the board of case-specific specialists. Removing the requirement for a board-certified psychiatrist also allows the agency to expedite the review board's convening in circumstances where a medical officer who is a board certified

psychiatrist is unavailable. By tailoring the board to meet the needs of the alien, HHS/CDC will ensure that the alien has the attention of medical officers who are experienced in the diagnosis and treatment of their specific medical condition.

## **V. Alternatives Considered**

This rulemaking is the result of HHS/CDC's annual retrospective regulatory review. Most of the proposed changes 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, 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 proposes to revise the definition of communicable disease of public health significance by removing these three uncommon health conditions: chancroid; granuloma inguinale; and lymphogranuloma venereum. We 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 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 proposed 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 proposed rule. First, we are proposing updates to the current regulation that 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 are proposing to remove 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 extremely 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.

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 the 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 the 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 and 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. None of the results are economically significant, e.g., none of the results are more than \$100 million a year in costs.

| Table 1. Annual Costs of Chancroid, Granuloma Inguinale, and Lymphogranuloma Venereum in Lawful Permanent Residents: 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 Total Annual Costs 50% comorbidity</u>   | \$18                          | \$2,122 | \$12,731       |
| <u>LPR Total Annual Costs NO comorbidity</u>  | \$33                          | \$3,858 | \$23,147       |



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 Estimate | Source Citation (RIA, Preamble, etc.) |
| BENEFITS   |                  |                  |                  |                                       |
| Monetized benefits   | NA (7%)          | NA (7%)          | NA (7%)          | RIA                                   |

|  |  |          |          |     |
|--|--|----------|----------|-----|
|  | NA (3%)  | NA (3%)  | NA (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> | NA (7%)  | NA (7%)  | NA (7%)  | RIA |
|  | NA (3%)  | NA (3%)  | NA (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 Estimate | Minimum Estimate | Maximum Estimate | Source Citation (RIA, Preamble, etc.) |
|--------------------|------------------|------------------|------------------|---------------------------------------|
| <b>BENEFITS</b>    |                  |                  |                  |                                       |
| Monetized benefits | NA (7%)          | NA (7%)          | NA (7%)          | RIA                                   |

|  |  |         |               |     |
|--|--|---------|---------------|-----|
|  | NA (3%)  | NA (3%) | NA (3%)       |     |
|  | NA (0%)  | NA (0%) | NA (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</sup> | NA (7%)  | NA (7%) | NA (7%)       | RIA |
|  | NA (3%)  | NA (3%) | NA (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.                         |  |         |               |     |

## 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 proposed rule on small businesses, small governmental units, and small not-for-profit organizations. We have analyzed the costs and benefits of this proposed 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 do expect this proposed 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.

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

HHS/CDC has determined that the proposed 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 proposed rule meets the standard in the Executive Order.

#### F. Executive Order 13132: Federalism

Under Executive Order 13132, if the proposed 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 proposed 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 proposing this rule to make our intentions and rationale clear and welcomes feedback from

the public on our attempt to use plain language in this rule.

### **VIII. 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 proposes to amend 42 CFR part 34 as follows:

1. Revise 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) a threat exists for importation into the United States, and (B) 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 revised 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) Gonorrhoea.

(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 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 the 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.



(1) 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 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 (b)(4) through (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 (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; and

(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 the 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 old 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 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 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:

(i) 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;

(ii) 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;

(iii) 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 option, 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: June 12, 2015.

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Sylvia M. Burwell  
Secretary

**[FR Doc. 2015-15236 Filed: 6/22/2015 08:45 am; Publication  
Date: 6/23/2015]**