

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 34

Docket No. CDC-2008-0001

RIN 0920-AA26

Medical Examination of Aliens - Removal of Human
Immunodeficiency Virus (HIV) infection from List of
Communicable Disease of Public Health Significance

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

ACTION: Notice of Proposed Rulemaking (NPRM)

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is proposing to amend its regulations governing medical examinations that aliens must undergo before they may obtain admission to the United States. HHS/CDC is proposing to amend the definition of "communicable disease of public health significance" and the scope of examinations to remove references to HIV. Aliens infected with a "communicable disease of public

health significance" are inadmissible into the United States under the Immigration and Nationality Act (INA). HHS/CDC is proposing to remove "Human Immunodeficiency Virus (HIV) infection" from the definition of communicable disease of public health significance. While HIV infection is a serious health condition, it does not represent a communicable disease that is a significant threat for introduction, transmission, and spread to the U.S. population through casual contact. An arriving alien with HIV infection does not pose a public health risk to the general population through casual contact. As a result of these proposed regulatory changes, aliens would no longer be inadmissible into the United States based solely on the grounds they are infected with HIV.

DATES: Written comments must be received on or before [INSERT DATE 45 DAYS AFTER PUBLICATION OF THE FEDERAL REGISTER NOTICE]. Comments received after [INSERT DATE 45 DAYS AFTER PUBLICATION DATE] will be considered to the extent possible.

ADDRESSES: You may submit written comments, identified by Docket No. CDC-2008-0001 to the following address: Division

of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, Attn: Part 34 NPRM Comments, 1600 Clifton Road, N.E., MS E-03, Atlanta, Georgia, 30333.

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.

Comments are also available for viewing at the following Internet addresses: <http://www.cdc.gov//ncidod/dq> and <http://www.globalhealth.gov>. You may submit written comments electronically via the Internet at the following Address: <http://regulations.gov>, or via email to Part34HIVcomments@cdc.gov.

To download an electronic version of the NPRM, please go to the following Internet address: <http://regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Stacy M. Howard, Division of Global Migration and Quarantine, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 1600 Clifton Road, N.E., MS E-03, Atlanta, Georgia 30333; telephone 404-498-1600.

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

- I. Legal Authority
- II. Background
- III. Summary of Proposed Changes to 42 CFR part 34
- IV. Required Regulatory Analyses under Executive Order 12866
- V. Regulatory Flexibility Analysis
- VI. Other Administrative Requirements

I. Legal Authority

HHS/CDC is promulgating this rule under the authority of 42 U.S.C. § 252 and 8 U.S.C. §§ 1182 and 1222.

II. Background

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. Those aliens outside the United States with a communicable disease of public health significance (see below) are ineligible to receive a visa and ineligible for admission into the United States. The grounds of inadmissibility for specified health-related grounds also pertain to aliens in the United States who are applying for adjustment of their status to that of a lawful permanent resident.

In addition to other potential grounds of inadmissibility, aliens are inadmissible if they are determined: 1) to have a communicable disease of public health significance (as currently defined by regulations); 2) to have 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; 3) to have had a physical or mental disorder and a history of behavior associated with the disorder, 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. Further, except for certain adopted children 10 years of age or younger, any alien who seeks admission as an immigrant, or seeks adjustment of their immigration

status to that of a lawful permanent resident, is inadmissible if the alien fails to present documentation of having received vaccination against vaccine-preventable diseases, including mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, Haemophilus influenzae type B, hepatitis B, and any other vaccination against vaccine-preventable disease recommended by the Advisory Committee for Immunization Practices (ACIP).

Medical examinations, including a physical and mental evaluation, to determine whether an alien could have such a health-related condition, are authorized under section 232 of the INA. (8 U.S.C. 1222) Under sections 212(a)(1) and 232 of the INA, and section 325 of the Public Health Service Act (42 U.S. C. 252), the Secretary of Health and Human Services (HHS) promulgates regulations establishing the requirements for the medical examination and lists the health-related conditions that make aliens ineligible for admission into the United States. The regulations, administered by the HHS/Centers for Disease Control and Prevention (CDC), are promulgated at 42 CFR part 34.

The provisions in 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; and 3) aliens required by the U.S. Department of Homeland Security (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 on a temporary basis, like 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.

On October 6, 2008, HHS/CDC revised part 34 to amend the definition of communicable disease of public health significance and revise the scope of the medical examination. This update addressed emerging and reemerging diseases in immigrant or refugee populations who are bound for the United States. See 73 FR 58047 and 73 FR 62210. The current definition of communicable disease of public health significance contained in 42 CFR 34.2(b) includes: 1) active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, lymphogranuloma venereum,

granuloma inguinale, and HIV infection; 2) quarantinable diseases designated by Presidential Executive Order; and 3) a communicable disease that may pose a public health emergency of international concern in accordance with the International Health Regulations of 2005, provided it meets specified criteria.

Panel physicians, designated by Department of State (DoS) consular officers, perform medical examinations on refugees and/or persons living outside of the United States who are seeking to immigrate to the United States, and civil surgeons, designated by U.S. Citizenship and Immigration Services within DHS, perform medical examinations for aliens who are already present in the United States seeking a change in status. Aliens determined to have a communicable disease of public health significance may request a waiver of inadmissibility to enter the United States under sections 207(c)(3), 212(d)(3)(A) and 212(g) of the INA (8 U.S.C. 1157(c)(3), 1182(d)(3)(A) and 1182(g)).

HHS/CDC issues Technical Instructions and provides the technical consultation and guidance to panel physicians and civil surgeons who conduct the medical examinations of

aliens. The CDC Technical Instructions for Medical Examination of Aliens, including the most current updates, which 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/ncidod/dq/technica.htm>.

Beginning in 1952, the INA mandated that aliens "who are afflicted with any dangerous contagious disease" are ineligible to receive a visa and are to be excluded from admission into the United States. In April, 1986, prior to the recent developments in medicine and epidemiologic principles, HHS proposed to include acquired immunodeficiency syndrome (AIDS) as a dangerous contagious disease and in June, 1987 issued a final rule adopting the proposal. 51 FR 15354 (April 23, 1986); 52 FR 21532 (June 8, 1987). Separately, HHS proposed to substitute HIV infection for AIDS on the list of dangerous contagious diseases since individuals who are so infected, but do not actually have AIDS, are also contagious. 52 FR 21607 (June 8, 1987). While the proposed rule was pending for public comment, HHS added HIV infection to its list of dangerous contagious diseases. Pub. L. No. 100-71, section 518, 101

Stat. 475 (July 11, 1987). HHS issued final regulations in August of that year complying with the congressional mandate. 52 FR 32540 (August 28, 1987) Accordingly and immediately, aliens infected with HIV became ineligible to receive visas and were excluded from admission into the United States because of infection with a dangerous contagious disease. See INA section 212(a)(6), 8 U.S.C. 1182(a)(6) (1988).

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 is excludable from the United States. Immigration Act of 1990, Pub. L. No. 101-649, section 601, 104 Stat. 4978 January 23, 1990; INA section 212(a)(1)(A)(i), 8 U.S.C. 1182(a)(1)(A)(i) (effective June 1, 1991). HHS/CDC subsequently published a proposed rule that would have removed from the list all diseases, including HIV infection, except for infectious tuberculosis. 56 FR 2484 (January 23, 1991). Based on comments received and reconsideration of the issues, HHS published an interim final rule retaining all diseases on the list, including

HIV infection, and committing its initial proposal for further study. 56 FR 25000 (May 31, 1991). Congress subsequently amended INA section 212(a)(1) to specify that "infection with the etiologic agent for acquired immune deficiency syndrome" is a communicable disease of public health significance, thereby making explicit in the INA that aliens with HIV are ineligible for admission into the United States. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, section 2007, 107 Stat. 122 (June 10, 1993).

In the summer of 2008, Congress amended the INA by striking "which shall include infection with the etiologic agent for acquired immune deficiency syndrome," thereby leaving to the Secretary of HHS the discretion for determining whether HIV should remain in the definition of communicable disease of public health significance provided for in 42 CFR 34.2(b). Tom Lantos and Henry Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Pub. L. No. 110-293, section 305, 122 Stat. 2963 (July 30, 2008). In this Notice of Proposed Rulemaking, HHS/CDC is proposing this action to remove HIV infection from the definition. While HIV infection is a serious health condition, it does not

represent a communicable disease that is a significant threat for introduction, transmission, and spread to the United States population through casual contact. An arriving alien with HIV infection does not pose a public health risk to the general population through casual contact. These changes reflect current scientific knowledge and public health best practices. If the rulemaking is finalized, infection with HIV would no longer be a ground of inadmissibility.

Annually, the U.S. Government admits more than 1,000,000 immigrants and refugees to reside permanently in this country.

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. The three 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); and 3) Employment-Based immigrants. There are also immigrant visas available to "Diversity" immigrants who obtain by lottery the ability to seek one of these visas. The immigration of immediate relatives is not subject to numerical restrictions; thus, an immigrant visa is available to an immediate relative upon approval of the citizen relative's visa petition. Each month, the U.S. Department of State (DoS) publishes a Visa Bulletin, indicating the availability of Family-Based, Employment-Based, and Diversity immigrant visas for the next month. The monthly Visa Bulletin is available on the Department of State's website (<http://travel.state.gov>).

Aliens who are already in the United States may apply to adjust to permanent resident status pursuant to these same family-based, employment-based categories described above, as well as several other statutorily-eligible adjustment categories. See *INA*, § 245; 8 U.S.C. 1255. Refugees and aslyees also apply to adjust to permanent resident status from inside the United States. See *INA*, § 209; 8 U.S.C. 1159.

An alien seeking permanent residence, whether through an immigrant or refugee visa or through an adjustment of status, must undergo a medical examination to determine whether the alien is inadmissible on medical grounds. Overseas examinations are conducted by panel physicians designated by the Department of State. Applicants for adjustment of status to lawful permanent resident are required to have a medical examination conducted by a civil surgeon designated by U.S. Citizenship and Immigration Services. Under the proposed rule, testing for HIV infection would be eliminated from these medical examinations.

Additionally, Temporary Protected Status (TPS) is another immigration mechanism for eligible aliens who are in the United States and whose countries have been designated for TPS due to ongoing armed conflict, natural disasters, or certain other extraordinary and temporary conditions. INA § 244; 8 U.S.C. 1255a; 8 CFR Part 244. TPS applicants are also subject to the medical grounds of inadmissibility. If a TPS applicant is infected with HIV, the Department of Homeland Security (DHS) requires that the applicant be granted a waiver of inadmissibility before TPS can be granted.

Refugees are persons who cannot return to their country because of persecution or the well founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion. An applicant is preliminarily approved for refugee status overseas, but is only admitted as a refugee upon admission to the U.S. at a port of entry. A refugee is also subject to the medical grounds of inadmissibility and the medical examination requirements. See INA § 207; 8 U.S.C. 1157; 8 CFR Part 207.

Non-immigrant visa applicants are those who come to the U.S. for temporary visits. A medical examination is not routinely required as a condition for issuance of non-immigrant visas, but may be required at the discretion of the DoS embassy or consular office that is issuing the visa. Non-immigrant visas are issued by DoS.

HHS/CDC is proposing this action to remove HIV infection from the regulatory definition and from the scope of examination. If finalized, infection with HIV would no longer be a ground of inadmissibility.

III. Summary of Proposed Changes to 42 CFR Part 34

This proposed rule removes HIV infection from the list of communicable diseases of public health significance as defined in 42 CFR 34.2(b) and scope of examinations in 42 CFR 34.3. While HIV infection is a serious health condition, it does not represent a communicable disease that is a significant threat for introduction, transmission, and spread to the United States population through casual contact. An arriving alien with HIV infection does not pose a public health risk to the general population through casual contact. These changes reflect current scientific knowledge and public health best practices and will have the benefit of removing stigmatization of and discrimination against people who are HIV infected.

Section 34.2 (b) Communicable diseases of public health significance

This provision defines communicable disease of public health significance as a defined list including specific diseases and categories of diseases for which all aliens are inadmissible to the United States. HHS/CDC is proposing to remove human immunodeficiency virus (HIV)

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

As described above, inclusion of HIV in this definition is no longer statutorily mandated. As a result, the Secretary of HHS has the discretion to determine whether to leave HIV infection in the definition or remove it.

In consideration of epidemiologic principles and current medical knowledge regarding the mode of HIV transmission, HHS/CDC is proposing to take action to remove HIV infection from 42 CFR part 34 because HIV infection does not represent a communicable disease of public health significance. HIV is not a significant threat for introduction and spread through casual contact to the general U.S. population, where HIV infection already exists among the U.S. population as an endemic disease.

Under current regulatory requirements, aliens who test positive for HIV infection can apply for a waiver from DHS and, if granted such a waiver, are allowed admission into the United States or to adjust status.

Diseases transmissible through aerosol or respiratory droplets such as tuberculosis pose a much greater risk due to casual contact for introduction and spread in the U.S. population. While HIV infection continues to be a disease of public health concern throughout the world, HIV infection is preventable by avoiding high risk sexual contact or needle-sharing with HIV-infected persons.

The rationale for maintaining HIV infection as an excludable condition is no longer valid based on current medical knowledge and practice, scientific knowledge, and experience which has informed us on characteristics of the virus, the modes of transmission of HIV, and interventions for prevention and further spread of the virus. Indeed, HIV infection is not spread by casual contact, through the air, or from food, water or other objects. An HIV-infected person in a common public setting will not place another individual at risk. HIV is a fragile virus and cannot live for very long outside the body. The virus is not transmitted by mosquitoes, or through day-to-day activities such as shaking hands, hugging, or a casual kiss. HIV infection cannot be acquired from a toilet seat, drinking fountain, doorknob, eating utensils, drinking glasses, food, or pets.

HIV infection is transmitted among individuals in the United States almost exclusively by two mechanisms: unprotected sexual intercourse with an HIV-infected person and sharing needles or syringes contaminated with HIV. Mother-to-child transmission of HIV can also occur from an infected mother before or during birth or through breast feeding. Additionally, HIV can be transmitted through transfusion of blood or blood products infected with HIV. However, there has been continuous screening for HIV in all donated blood since 1985. Therefore, the risk for HIV infection through transfusion is extremely low. The U.S. blood supply is considered among the safest in the world.

Section 34.3 Scope of examinations

HHS/CDC is also proposing to remove all references to serologic testing for HIV infection in 42 CFR 34.3 which is entitled "Scope of examinations". This section applies to those aliens who are required to undergo a medical examination for U.S. immigration purposes. The scope of examinations outlines those matters that relate to the inadmissible health-related conditions. This section provides specific screening and testing requirements for

those diseases that meet the current definition of communicable diseases of public health significance and directly relates to the diseases list in Section 34.2 (b) of 42 CFR Part 34. It does not provide specific screening and testing requirements for other health-related conditions which are not included in the current definition of communicable diseases of public health significance. Therefore, HHS/CDC is proposing to remove the specific screening and testing requirements for HIV infection in 42 CFR 34.3.

IV. Required Regulatory Analyses under Executive Order

12866

HHS/CDC has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act (Pub. L. 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is an economically significant action under the Executive Order.

A. Objectives and basis for the action

As stated previously in the Summary, HHS/CDC is proposing to take this action to reflect current scientific knowledge and public health best practices and to reduce stigmatization of and discrimination against people who are HIV-infected. This proposed rule is not intended to correct any market failure. The benefits accounted for in the impact analysis are qualitative and reflect non-economic benefits of the rule.

B. The Nature of the Impact

To evaluate the potential costs and benefits of allowing HIV-infected aliens to enter the United States, we assessed the economic impact on the health care system in the United States of removing HIV from the list of specific communicable diseases of public health significance and removing the HIV testing requirement in the medical examination for aliens who are applying for adjustment of their status to that of a lawful permanent resident. The benefits we considered include reducing discrimination based on HIV status. We are seeking comments on the economic impact analysis, including the identification of

potential data sources that would allow us to more precisely estimate the impact of the proposed rule.

C. Defining the population affected

The proposed changes in the medical examination of aliens regulations affects all visitors to the U.S. who are infected with HIV. Although HIV testing is not routinely required for entrance into the U.S. except for those aliens who are seeking to become lawful permanent residents, visitors who are infected with HIV are required to request waivers to obtain entrance. Data on the number of waivers granted annually are not available but costs to obtain waivers are thought to be minimal. Thus, this analysis is limited to aliens seeking to become lawful permanent residents and, thus, are required to have a medical examination to determine admissibility. The affected population is defined as the number of new HIV-infected lawful permanent residents entering the United States each year and those individuals already in the United States seeking to adjust their immigration status to that of a lawful permanent resident. Entry into the U.S. includes those aliens who are already in the U.S. and adjust their status to that of permanent legal resident.

Using data sources describe below, we estimated that approximately 4.06 immigrants per 1000 immigrants that would be likely to enter the U.S. under the proposed rule would be infected with HIV. Using data from the 2007 Immigration Statistics, this is equivalent to approximately 4275 HIV-infected immigrants who would enter into the United States each year. These numbers are based on the estimated distribution of HIV/AIDS cases in each of the regions in the world and weighted by the number of immigrants entering the United States from each region. The numbers of HIV/AIDS persons in each region of the world were taken from the 2007 AIDS Epidemic Update: Global Overview issued by the Joint United Nations Programme on HIV/AIDS (UNAIDS). HHS/CDC used regional data and rates were determined using the regional population data from 2006 published by the Population Division of the Department of Economic and Social Affairs of the United Nations Secretariat. After examining the immigration data, by region, from the Yearbook of Immigration Statistics: 2007 Immigrants, we assigned regional weights according to the number of aliens coming to the United States from each region. (See Section G. Number of HIV-infected cases) Because no data exist indicating that the HIV prevalence in persons seeking to immigrate to the U.S. differs from the

general regional population prevalence we assumed that it would be equivalent to the regional HIV prevalence rates. We used regional HIV prevalence rates rather than HIV rates for specific countries to allow for year to year variations in the number of aliens entering the U.S. from specific countries. We also conducted extensive sensitivity analyses to assess the impact of altering this assumption. Because the impact to the proposed rule change is highly sensitive to HIV prevalence in aliens entering the U.S. we are seeking comment on these assumptions.

D. Baseline

The baseline for this analysis assumes no change in the current regulation. In other words, all applicants for admission into the U.S. as legal permanent residents and those already within the U.S. seeking adjustment to permanent resident status are tested for HIV during the immigration medical exam. Those who are HIV-infected and are not granted a waiver by the Department of Homeland Security are refused lawful permanent resident status in the United States.

Currently, refugees who are HIV-infected must be granted a waiver by the Department of Homeland Security before

entering the U.S. Subsequently, refugees infected with HIV who are present in the U.S. and apply for adjustment to permanent resident status must be re-examined and granted another waiver from DHS at that time (i.e., the grant of waivers permits these individuals to obtain refugee status, and later, permanent resident status despite being HIV-infected, which would otherwise render them inadmissible). We have not included these HIV-infected refugees-turned-permanent residents in the model, however, because: i) these persons, compared to the other immigrants, enter the U.S. under extraordinary circumstances; ii) the numbers are relatively small; and, iii) the proposed change in regulations will not have a significant impact on the annual number of HIV-infected refugees admitted to the U.S. and who later become permanent residents because such persons generally receive a waiver of inadmissibility for HIV infection under current procedures. Thus, the numbers of admitted HIV-infected refugees who are subsequently granted permanent resident status are likely to stay the same, regardless of regulations in place. That is, the HIV-infected refugees-turned-permanent residents are part of the baseline scenario.

E. Alternatives

HHS/CDC examined three regulatory approaches.

1. The first approach is to maintain HIV infection on the list of communicable disease of public health significance, i.e., to keep the disease as an excludable condition for entry into the U.S. This means that visa applicants seeking permanent residency would continue to undergo testing for HIV infection as part of the application process. Those applicants testing positive for HIV would still be required to apply for and obtain a waiver from DHS prior to coming to the U.S. There are several disadvantages to this approach. As stated previously, while HIV infection is a serious health condition, it does not represent a communicable disease that is a significant threat for introduction, transmission, and spread to the U.S. population through casual contact. Thus, maintaining HIV infection on the list of excludable conditions for entry into the U.S. would not result in measurable public health benefits. Further, this approach is not in line with current international public health practice. This approach continues discriminatory practices and contributes toward the stigmatization of HIV-infected persons. HHS/CDC did not select this approach.

2. The second approach is to remove HIV infection from the list of communicable disease of public health significance, i.e. remove it as a ground of inadmissibility into the U.S., but continue mandatory HIV testing for all immigrant applicants. Under this approach, all those aliens who test positive for HIV infection would be counseled regarding their conditions, the need for appropriate treatment, and the steps that should be taken to minimize the risk of onward transmission.

There are benefits to this approach. HIV-infected aliens who are unaware of their HIV status would become aware of their status. Early diagnosis and treatment of HIV-infected persons can increase life expectancy and may improve the quality of life. Additionally, knowing one's HIV status decreases the likelihood of onward transmission (1,2).

There are also impediments and disadvantages to this approach. First, section 212(a)(1)(A)(i) of the INA does not appear to allow HHS/CDC to impose a mandatory HIV testing condition if HIV infection is removed from the definition of a communicable disease of public health

significance. In fact, mandatory testing for other serious health-related conditions, i.e., infectious diseases, such as hepatitis, malaria, and West Nile virus, are not required as part of this medical examination. Second, while the purpose of the medical examination has been to identify health conditions considered inadmissible on public health grounds, the results might not be kept confidential because panel physicians may be required by statutes in the country of origin to report HIV results. Finally, requiring mandatory HIV testing in a context where the underlying disease is not a communicable disease of public health significance is inconsistent with the current practice for HIV screening in the United States. HHS/CDC did not select this approach and specifically request comments on the benefits and impediments to this approach.

3. The third approach is to remove HIV infection from the list of communicable disease of public health significance and as a requirement in the medical examination. This means that mandatory testing for HIV infection would no longer be required and DHS would allow HIV-infected persons to enter into the U.S. (or to adjust to permanent resident status) if they meet all other conditions. This is the regulatory approach that HHS/CDC

selected. HHS/CDC will investigate how to best promote voluntary HIV screening for immigrants, non-immigrants, refugees, and other migrants consistent with its recommendations for all Americans age 13-64. The discussion of benefits and costs that follow relate to this approach.

F. Benefits

HHS/CDC is proposing to remove HIV infection from the definition of communicable disease of public health significance contained in 42 CFR part 34.2(b) and scope of examination, 34.3 because HIV infection does not represent a communicable disease that is a significant threat to the general U.S. population. The rationale for maintaining HIV infection as an excludable condition is no longer valid based on current medical knowledge and public health practice, scientific knowledge, and experience which has informed us on the characteristics of the virus, the modes of transmission of HIV, and the effective interventions to prevent further spread of the virus.

This proposed rule will bring family members together who would be barred from entry, thus strengthening families. Also, immigrants with skills in high demand who

otherwise would be denied entry would be permitted to enter the U.S. on a permanent basis to seek employment.

Depending on the region of the world from which a person emigrates, admittance to the U.S. may afford greater opportunity, better health care, and education and training programs than those available in the immigrant's home country.

Further, this proposed rule to remove HIV infection from the list of communicable disease of public health significance and from the scope of examinations will remove stigmatization of and discrimination against HIV-infected people. This proposed rule will also bring the U.S. in line with current science and international standards of public health practice.

G. Costs

The proposed rule will potentially result in an increased number of HIV-infected immigrants to the U.S. each year. The costs associated with the proposed rule include the increased health care costs associated with treating HIV infection in immigrants and persons who become infected due to onward transmission, the costs of social

services for HIV-infected immigrants and persons who become infected due to onward transmission who become unable to fully support themselves because of their illness, the costs of decreased productivity among employed HIV-infected immigrants and persons who become infected due to onward transmission who become too sick to work, and the decreased costs of the medical exam because HIV testing is no longer required for those persons within the U.S. seeking to change their status to that of lawful permanent resident. Because health care costs are substantial and no data exist for estimates of other costs listed above, this analysis is limited to health care costs associated with treatment of HIV infection.

Description of the Model

Our model considers the potential health care costs from admitting HIV-infected immigrants into the U.S. It compares such costs to the baseline (i.e. Alternative 1 above) which is no admittance, except pursuant to a waiver, of HIV-infected persons as immigrants or the adjustment of such individuals to permanent resident status within the U.S. We built the model, titled HIVEcon, using standard

software (Microsoft Excel, Microsoft Corp, Redmond, WA¹). Essentially, the model estimates the number of potential HIV-infected immigrants that may arrive in the U.S. or be adjusted to permanent resident status within the U.S. (under the new proposed rule). The model then calculates the lifespan of such HIV-infected immigrants, building a survival curve (i.e., probability of survival to a given age), assuming that they receive the appropriate treatment in the U.S. that will extend their lifespan. Using the estimated number of HIV-infected immigrants and adjusted permanent residents and the estimated lifespan, the model then estimates the costs of treating those HIV-infected immigrants and adjusted permanent residents in the United States over their lifespan. For the economic analysis we established a primary (or base) case using the best science available for parameter estimates. Because data were not available for most of the parameters in our analysis we established lower and upper bounds for those parameters for which variation had the greatest impact on the results.

The model, HIVEcon, examines the health care costs associated with newly identified persons infected with HIV

¹ Note: Microsoft Excel is a copyrighted product produced by Microsoft Corporation, Redmond, Washington. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

regardless of payer. The calculations reflect the total health care costs for HIV-infected immigrants arriving in the U.S. and persons who become infected due to onward transmission for appropriate treatment which extends the lifespan. The calculations further assume that all HIV-infected immigrants arriving in the U.S. and persons who become infected due to onward transmission would receive the current standard of care for the treatment of HIV.

We assumed that there would be no changes in the current standard of care for HIV treatment over time. That is, the treatment of HIV infection will remain in its current form and will not advance beyond the current level of treatment. Additionally, in analyzing the longevity of persons infected with HIV, the analysis assumes no improvement in the treatment of HIV infections over time. Thus, the possibility that the life span of infected individuals will increase with improved treatment is not considered.

We used 30 years as the average age of HIV-infected immigrants. Because no data exist on this parameter we conducted sensitivity analyses using 20 years and 40 years as the lower and upper bound. The average age for persons

with HIV infection in the U.S. is approximately 40 years (based on calculations from the table AIDS cases by age *HIV/AIDS Surveillance Report: Cases of HIV Infection and AIDS in the United States and Dependent Areas, 2006*) (3). The median age of the lawful permanent resident in the U.S. is between 40 and 44 years (4). The median age of the general U.S. population is between 25 and 30 years (5).

Model Inputs

The model, HIVEcon, consists of the following components or inputs: 1) prevalence of HIV in regions from which immigrants to the U.S. originate; 2) projected number of immigrants, by region, entering the U.S. annually; 2b) annual percentage change in number of immigrants arriving in the U.S. compared with the baseline; 3) estimated onward transmission rates of HIV infection from HIV-infected immigrants to the U.S. population; 4) estimated survival analysis for the HIV-infected persons living in the U.S.; 5) annual discount rate (3% and 7%); 6) estimated average age of HIV-infected immigrant upon arrival in the U.S.; and 7) the projected annual cost of treating an HIV-infected patient in the U.S.

Table 1: Summary of Model, HIVEcon, Inputs and Assumptions
for Primary, Lower and Upper Bound Analyses*, †

Inputs and Assumptions	Values
Perspective of study	Societal
HIV-infection survival over time§	Average life expectancy at: Age 20 years - 28.6 years (Lower bound) Age 30 years - 24.7 years (Primary) Age 40 years - 19.9 years (Upper bound)
Number of immigrants entering U.S. annually	1,052,415 (6)
Annual percent change in number of immigrants arriving in the U.S. †	0%
Weighted rate of HIV-infected immigrants (potential) per 1,000 applicants assuming immigrant population HIV prevalence is equivalent to HIV prevalence of general population of region of origin	4.06 /1000 immigrants (Primary) 1.02/1000 immigrants (Lower bound) 6.09/1000 immigrants (Upper bound)
Average age of HIV-infected immigrant upon entry into U.S.	20 years (Lower bound) 30 years (Primary) 40 years (Upper bound)
Annual Transmission rate per 100 HIV-infected persons assuming rate per HIV-infected immigrants is half of that of U.S. HIV-infected population(7)	0 cases induced annually per 100 HIV-infected immigrants (Lower bound) 1.51 cases induced annually per 100 HIV-infected immigrants (Primary) 4.53 cases induced annually per 100 HIV-infected immigrants (Upper bound)
Annual cost of HIV therapy per HIV-infected person in the U.S.	\$25,200 (8) (\$19,466 lower estimate; \$30,954 upper estimate)
Annual discount rate	3%, 7%

Notes:

* See the appropriate section of the main text for additional details and data sources.

†The model, HIVEcon, is available as a Technical Appendix (see source listed in References), and a reader can determine the relative impact of altering almost any input value, individually or several simultaneously.

§ The model contains a complete survival-over-time curve. The numbers given in this table are samples of the life expectancy derived from the survival curve. See the appropriate section in the main text for the complete survival curve.

†HIVEcon allows, as with almost all inputs, the user to change this baseline estimate

Data sources; See the appropriate sections in the main text for data sources.

Number of HIV-infected cases

i) Data Input: Estimated prevalence of HIV in regions from which immigrants to the U.S. originate: In HIVEcon we assume that HIV prevalence among immigration applicants is the same as that of the populations in the regions in the world where the immigrants come from. HHS/CDC calculated HIV rates for each of the regions of the world using the

World Population Estimates of the United Nations Population Division (9) and the UNAIDS 2007 AIDS Epidemic Update (10).

ii) Data Input: Number of immigrants, by origin, arriving annually in the U.S. HIVEcon uses data regarding immigrants into the U.S. from the 2007 Demographic and Health Surveillance Yearbook of Immigration Statistics (11). HIVEcon divided immigrants into the U.S. as having come from one of six regions: Africa, Asia, Europe (East and West), North America, Oceania, and South America (including Central America and Caribbean).

iiia) Calculation: Number of HIV-infected immigrants arriving annually in the U.S.

Equation 1: For a given region: Number of estimated HIV-infected immigrants arriving in the U.S = (number of adults and children living with HIV / population of region) x number of all immigrants from region.

Equation 2: Total Number of HIV-infected immigrants arriving in the U.S. = Sum of numbers of estimated HIV-infected immigrants from all 6 regions.

iib) Calculating upper and lower bounds for the number of estimated HIV-infected immigrants from each region were derived by taking the 5th and 95th percentiles (high and low estimates) of the number of estimated HIV-infected persons in each region but weighted by the number of lawful permanent residents who entered the US in 2007. The general equation, for each region, is as follows:

Equation 3: For a given region: Lower bound of number of HIV-infected immigrants arriving in the U.S = (low estimate of number of adults and children living with HIV / population of region) x number of all immigrants from that region in 2007.

Equation 4: Total, low estimate of number of HIV-infected immigrants arriving in the U.S. = Sum of low estimates of numbers of HIV-infected immigrants from all 6 regions.

We used a similar set of equations to calculate an upper bound of HIV-infected immigrants who will arrive in the U.S. under the new regulation.

iic) Data input: Annual change in the projected number of immigrants: An assumption was made, for the purposes of

this model, that the number of immigrants to the US will remain constant for the period of analysis (50 years). Readers can change this assumption in HIVEcon (see Technical Appendix I).

iii) Data input: Estimated onward transmission rate from HIV-infected immigrants to U.S. population. This calculation within HIVEcon estimates for the number of new infections among the existing U.S. population that might occur as a result of the arrival of HIV-infected immigrants. HIVEcon uses the following general equation to calculate estimated the number of new HIV cases caused by onward transmission from HIV-infected immigrants:

For a cohort of HIV-infected immigrants that arrive in the U.S. in Year Y:

Equation 5: Number of estimated HIV-infected cases due to onward transmission (in Year t) = (Number of HIV-infected immigrants + U.S. persons previously infected by onward transmission from HIV-infected immigrants that survive to Year t) x onward transmission rate.

Note that, for the purposes of calculating new HIV infections associated with HIV-infected immigrants in the U.S., HIVEcon adds persons infected by HIV-infected immigrants to the cohort of projected HIV-infected immigrants. This modeling technique represents the chain of onward transmission after initial transmission from an HIV-infected immigrant.

HIVEcon's value for the primary analysis for the rate of onward transmission is 1.51% to represent the annual estimated number of new infections caused by HIV-infected immigrants to the U.S., or caused by U.S. person infected by HIV-infected immigrants (i.e., annually every 100 HIV-infected persons infect an additional 1.51 persons). The most recent estimate of average onward transmission in the United States is 3.02 %.(7) However, multiple studies of HIV infection among immigrant populations indicate that these groups have less risky social behaviors and more restricted and closed social networks than those in the general U.S. population. Thus, onward transmission rates are likely to be lower. For this analysis, we assumed that the onward transmission rate for immigrants would be fifty percent of the average U.S. rate (1.51%). Because data supporting this assumption are limited, this assumption was

tested in sensitivity analysis. We used no transmission as our lower bound estimate and a transmission rate of 4.53 per 100 HIV-infected immigrants as our upper bound estimate. The upper bound transmission rate is a fifty percent increase in the average annual onward transmission rate of 3.02%. HIVEcon allows the user to change the assumed rate of onward transmission (See Technical Appendix I). The results of further sensitivity analysis on the onward transmission rate are also provided in the Table 3. We are seeking comment on this assumption.

It should also be noted that, in HIVEcon, the estimate of the average annual transmission percent remains constant over the lifespan of an HIV-infected person. In fact, there is evidence that indicates that HIV prevalence, and thus possibly incidence, varies by age and population (10). In effect, using a constant risk of onward transmission implies that the risk of transmission used represents an age-weighted average risk based on the U.S. experience.

iv) Data input: Survival analysis for HIV-infected persons
Survival curves used in HIVEcon for both the general US population and those for HIV infected patients are presented in Technical Appendix II Figure II.1b.

Equation 6: Estimated number of HIV-infected person surviving in Year t = (Number from cohort in Year $t-1$) x probability of surviving from year $t-1$ to year t .

We calculated survival probabilities in 5 year increments (e.g., at age 5 years, at age 10 years, etc.). Thus, when calculating the probability of surviving from one year to the next, for those years between each 5 year estimate (e.g., year 6, year 11), we assumed that the annual survival probability remained constant until the next 5 year period (e.g., for age 10 years through 14 years, we used the same probability of surviving from year t to year $t+1$).

Note that, as described in the section on onward transmission rate (section iii, earlier), those in the U.S. infected by HIV-infected immigrants are added, each year, to the HIV-infected cohort. We essentially assumed those so infected by onward transmission (directly from HIV-infected immigrants or from those US person previously infected by HIV-infected immigrants) are of a similar age as the HIV-infected immigrants, and thus join the survival curve at the same point as the HIV-infected immigrants.

iv) Data input: Sensitivity analysis: Impact on cumulative total of HIV cases in year 20.

We conducted extensive sensitivity analyses to determine the relative importance of rate of HIV positive immigrants and the rate of onward transmission. We varied the rate of HIV positive immigrants from the primary estimate of 4.06/1,000 immigrants (Table 1) in steps of +/- 25%.

Simultaneously, we varied the rate of onward transmission from the primary estimate of 1.51% per year (Table 1) in steps of +/- 25%. We also considered the impact of different average ages of entry, with 30 years as the primary case and 20 years and 40 years as the lower and upper limits, respectively.

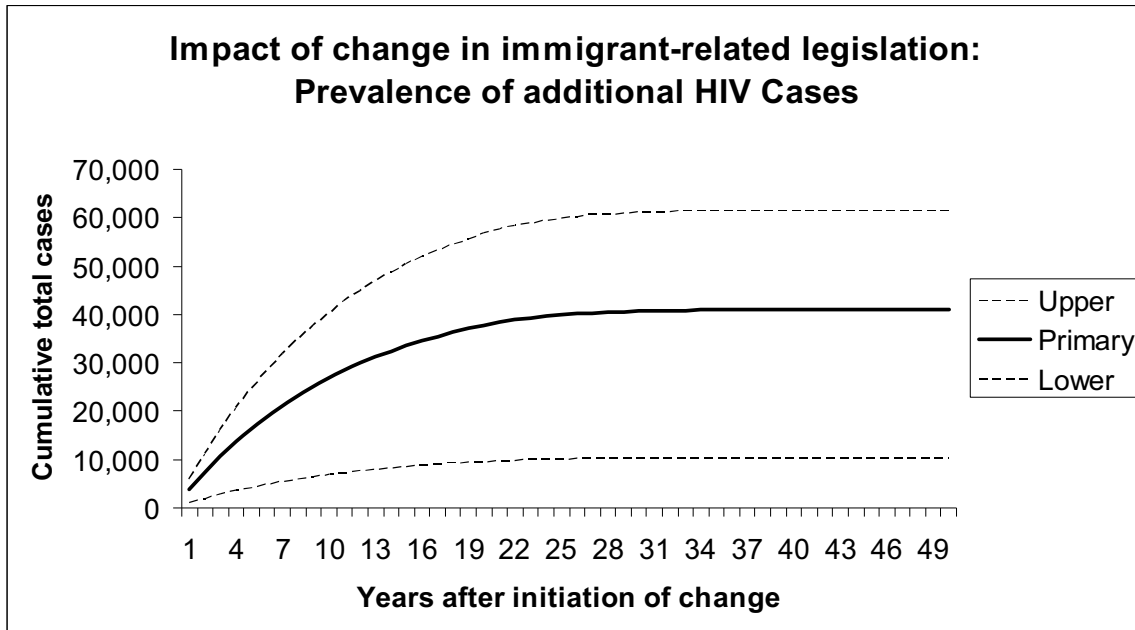
Results: Number of HIV-infected cases

i) Number of estimated HIV-infected immigrants arriving each year in the U.S.: Using 2007 data, in our primary analysis (assuming average age of entry is 30 years) it is estimated that 4,275 HIV-infected persons would immigrate each year to the U.S.; the lower bound estimate is 966 and the upper bound estimate is 5,768 persons. This is equivalent to a rate of 4.06 infected persons per 1,000

immigrants (lower bound of 1.02 to upper bound of 6.09 HIV-infected persons per 1,000 immigrants).

ii) Results: Number of estimated total new HIV-infected cases in the U.S. (immigrants plus U.S. person infected due to onward transmission): Assuming an average age of arrival of 30 years, after the first 20 years post initiation of the new regulations, the cumulative number of estimated, additional HIV-infected persons in the U.S. will be 37,780 cases (lower bound 9,487; upper bound 56,645). This number includes both the arrival of HIV-infected immigrants and those infected in the U.S. due to onward transmission, assuming a rate of onward transmission of 1.51% per year (Figure 2).

Figure 1: Cumulative total estimated HIV-infected immigrants, plus those U.S. persons infected due to onward transmission, in the U.S. due to changes in immigration regulations: Primary, upper and lower bound estimates: Average age of arrival 30 years*§



Notes:

* Primary estimate calculated using a weighted average rate of 4.06 HIV-positive per 1,000 immigrants. Infection rates of 6.09/ 1,000 and 1.02/1,000 used to calculate the upper and lower bound estimates, respectively.

§ The rate of onward transmission was 1.51%. Those infected by onward transmission are included in the totals above.

Source: Calculated using HIVEcon. See main text for details, and Technical Appendix II, Table 11.3.

Figures 2a and 2b: Cumulative total HIV-infected immigrants, plus those U.S. persons infected due to onward transmission, in the U.S. due to proposed changes in

immigration regulations: Base, high and low estimates:
 Average age of entry 20 years (2a) and 40 years (2b)*§

Figure 2a: Average age of entry 20 yrs

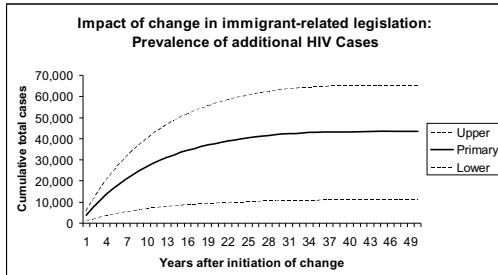
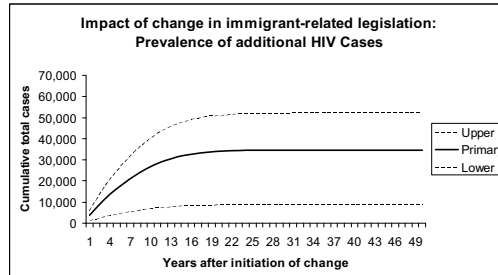


Figure 2b Average age of entry 40 yrs



Notes:

*Primary estimate calculated using a weighted average rate of 4.06 HIV-infected per 1,000 immigrants. Infection rates of 6.09/ 1,000 and 1.02/1,000 used to calculate the upper and lower bound estimates, respectively.

§ The rate of onward transmission was 1.51%. Those infected by onward transmission are included in the totals above.

Source: Calculated using HIVEcon. See main text for details.

Increasing the average age of entry of HIV-infected immigrants to 40 years, after the first 20 years post initiation of the new regulations, the number of additional HIV-infected persons in the U.S. will be approximately 34,029 cases (lower bound: 8,545; upper bound 51,021). This number includes both the arrival of HIV-infected immigrants

and those infected in the U.S. due to onward transmission (Figure 2b).

Decreasing the average age of entry of HIV-infected immigrants to 20 years, after the first 20 years post initiation of the new regulations, the number of estimated additional HIV-infected persons in the U.S. will be approximately 37,780 cases (lower bound: 9,487; upper bound: 56,645) This number includes both the arrival of HIV-infected immigrants and those infected in the U.S. due to onward transmission (Figure 2a).

Thus, given the other assumptions (Table 1), the assumed average age upon entry of HIV-infected immigrants, particularly if the age of entry is assumed to be older than 30 years, can impact the estimated numbers of those living in the U.S. with HIV due to the arrival of HIV-infected immigrants.

iii) Results: Number of total U.S. persons infected due to onward transmission: Removing the effects of onward transmission (done by simply setting, in HIVEcon, the rate of onward transmission to 0.0%), after 20 years from initiation of the new regulations, the number of HIV-

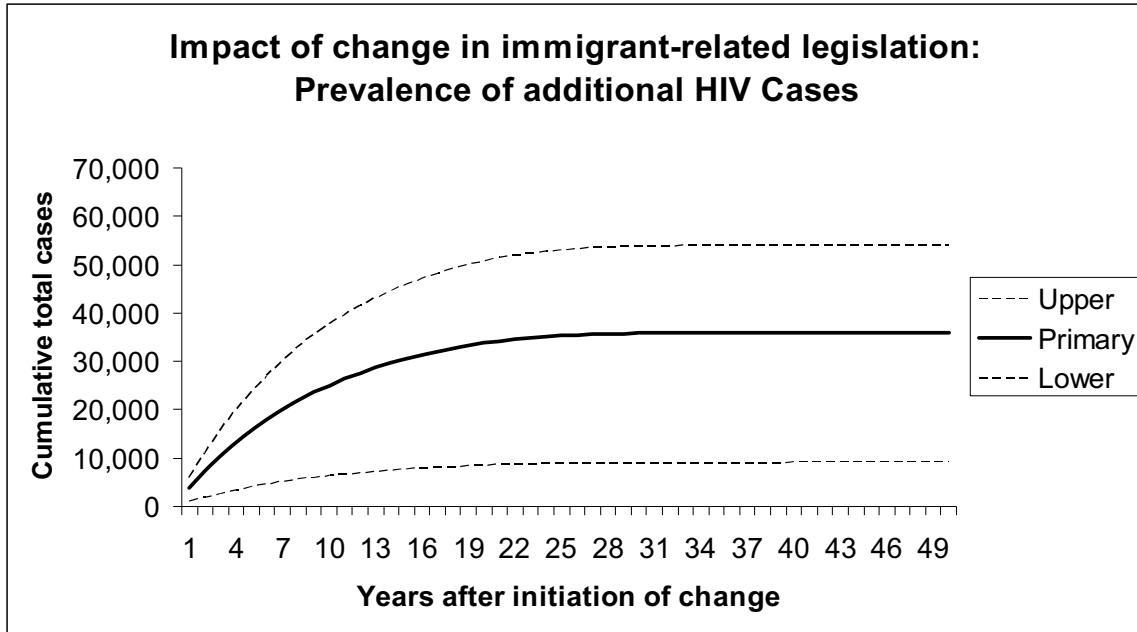
infected immigrants in the U.S. will be approximately 33,795 persons (lower bound: 8,487; upper bound: 50,670) (Figure 3).

Subtracting the number of estimated HIV-infected immigrants in year 20 in the U.S. from the total number of HIV-positive cases in the U.S. (Figure 2) gives approximately 3,985 U.S. persons (lower bound: 1,000; upper bound: 5,975) living with HIV following the arrival of HIV-positive immigrants (in year 20, after enacting the new regulations) (Figure 4).

The number of HIV-infected immigrants using the lower and upper bound estimate of prevalence, transmission, and age upon entry into the U.S. are presented in the Technical Appendix II (Figures II.2a and II.2b, Tables II.4 and II.5). The numbers of U.S. persons with HIV following the arrival of HIV-infected immigrants are also presented in the Technical Appendix II (Figures II.3a and II.3b, Tables II.4 and II.5).

Figure 3: Cumulative total HIV-infected immigrants, excluding those infected due to onward transmission, in the U.S. due to changes in immigration regulations: Primary,

lower, and upper bound estimates: Average age of arrival 30 years*§



Notes:

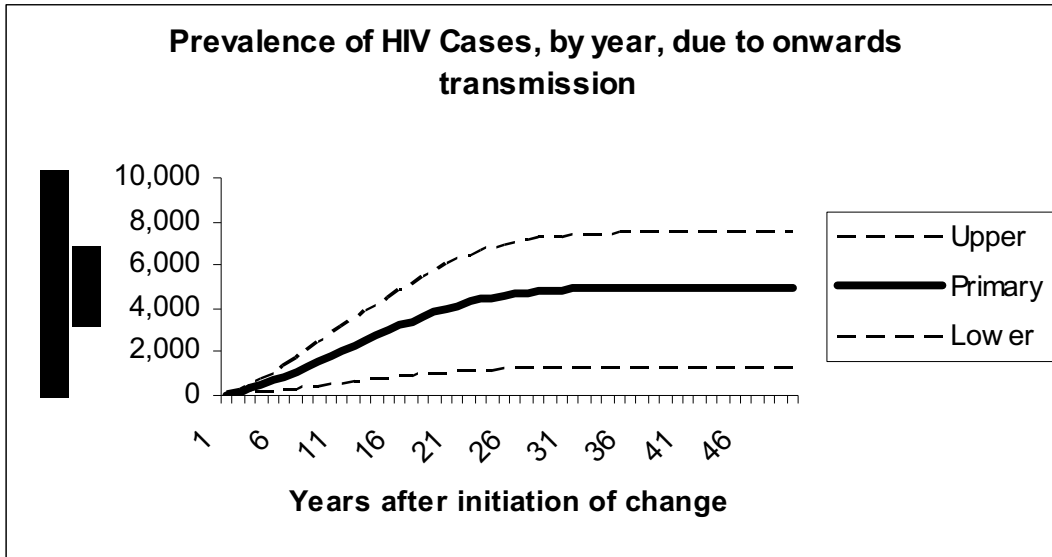
* Primary estimate calculated using a weighted average rate of 4.06 HIV-positive per 1,000 immigrants. Infection rates of 6.09/ 1,000 and 1.02/1,000 used to calculate the upper and lower bound estimates, respectively.

§ For these estimates, no onward transmission is assumed.

Source: Calculated using HIVEcon. See main text for details, and Technical Appendix II, Table 11.3.

Figure 4: Cumulative estimated total HIV-infected U.S. persons (only), infected due to onward transmission (1.51% annual transmission rate), due to changes in immigration

regulations: Primary, upper and lower bound estimates:
 Average age of arrival 30 years*§



Notes:

* Primary estimate calculated using a weighted average rate of 4.06 HIV-positive per 1,000 immigrants. Infection rates of 6.09/ 1,000 and 1.02/1,000 used to calculate the upper and lower bound estimates, respectively

§ For these estimates, onward transmission is assumed to be at a rate of 1.51%. For the purposes of calculating new HIV-infected U.S. persons due to HIV-infected immigrants, HIVEcon adds those U.S. persons who are infected by HIV-infected immigrants to the HIV-infected immigrant cohort, and thus are able to onward transmit to other U.S. persons.

Source: Calculated using HIVEcon. See main text for details, and Technical Appendix II, Table 11.3.

iv) Results: Numbers of new estimated HIV cases each year in the U.S. (incidence): the number of new projected HIV cases that could occur in the U.S. each year due to HIV-infected immigrants arriving comprises of two components: i) The number of projected HIV-infected immigrants newly arriving in the U.S.; and, ii) The number of persons infected by onward transmission either directly from the HIV-infected immigrants, or from persons who have previously been infected by HIV-infected immigrants.

The number of estimated persons infected by onward transmission: The estimated annual number of new HIV infections due to onward transmission by HIV-infected immigrants is presented in Table 2a-c. The number of new infections is impacted by the assumed average age upon entry of HIV-infected immigrants (Table 2). Detailed Tables of annual HIV incidence by years post enactment of the new regulation are provided in the Technical Appendix II (Tables II.6, II.7 and II.8),

Table 2a-c: Annual estimated numbers of new infections following arrival of HIV-infected immigrants: Annual estimated new infections by average age upon entry of HIV-infected immigrants.

Table 2a: Estimated new infections from onward transmission in the U.S.: Average age upon entry of HIV-infected immigrants: 20 years.

Years post enactment	Numbers of new HIV infections due to onward transmission		
	Lower	Primary	Upper
1	16	65	97
5	68	272	407
10	112	444	666
20	157	624	936
50	181	721	1082

Table 2b: Estimated new cases of onward transmission in the U.S.: Average age upon entry of HIV-infected immigrants: 30 years.

Years post enactment	Numbers of new HIV infections due to onward transmission		
	Lower	Primary	Upper
1	16	65	97
5	68	272	407
10	112	444	666
20	157	624	936
50	172	683	1024

Table 2c: Estimated new cases of onward transmission in the U.S.: Average age upon entry of HIV-infected immigrants: 40 years.

Years post enactment	Numbers of new HIV infections due to onward transmission		
	Lower	Primary	Upper

1	16	65	97
5	68	272	407
10	112	444	666
20	144	575	862
50	148	589	883

Notes: i) The primary case was estimated using a weighted average rate of 4.06 HIV-infected per 1,000 immigrants.

Infection rates of 1.02/ 1,000 and 6.09/1,000 are used to calculate the lower and upper bound estimates, respectively.

ii) For these estimates, onward transmission is assumed to be at a rate of 1.51%. For the purposes of calculating new HIV-infections due to HIV-infected immigrants, HIVEcon adds those persons who are infected by HIV-infected immigrants to the HIV-infected immigrant cohort, and thus are able to onward transmit to other persons.

Source: Calculated using HIVEcon. See main text for details, and Technical Appendix II, Tables II.6, II.7 and II.8.

In year 20 post promulgation of the new regulation, assuming an average age of HIV-infected immigrants of 30 years, there will be approximately 4,899 new HIV infections in the U.S. This is calculated by using the primary

estimate of 624 new infections among persons in the U.S. (only) due to arrival of HIV-infected immigrants (Table 2b, year 20 post enactment of the new regulations), and the primary estimate of 4,275 new HIV-infected immigrants who could be arriving each year (Results, part i).

For comparison, in 2006, an estimated 56,300 new HIV infections occurred in the U.S. (13). Thus, the 4,899 new (annual) HIV infections estimated to be attributed to HIV-infected immigrants 20 years after the promulgation is equivalent to 8.7% of the annual HIV incidence that occurred in the U.S. in 2006.

v) Results: Sensitivity analysis: Impact on cumulative total of HIV cases in year 20. The sensitivity analysis (Table 3) illustrates that assumed rate of HIV positive immigrants per 1,000 immigrants is the most important variable determining the number of additional HIV cases in the U.S. (at year 20). For example, increasing the rate of onward transmission from 0.75% to 4.53% (a 500% difference) will increase the number of HIV cases by approximately 34%. Yet increasing the rate of HIV positive immigrants per 1,000 immigrants from 1.02 to 6.09 (approximately a 500%

difference) will increase the number of cases by approximately 500%.

Table 3. Sensitivity analysis: Cumulative total^a number of HIV+ immigrants and HIV cases due to onward transmission in year 20^b; Average age at entry 30 years (20 years; 40 years)^c

Cumulative total of HIV cases at year 20 due to immigration and onward transmission assuming:
Average age at entry: 30 years (20 years; 40 years)
Onward transmission rate (per 100 HIV+ immigrants)^d

		0	.75	1.51	2.27	3.02 ^e	3.78	4.51
immigrants, per 1000 immigrants to the United States	1.02	8,449	8,928	9,445	10,004	10,607	11,261	11,960
		(8,449; 7,714)	(8,928; 8,098)	(9,445; 8,507)	(10,004; 8,945)	(10,607; 9,413)	(11,261; 9,913)	(11,960; 10,444)
	2.03	16,898	17,856	18,890	20,007	21,215	22,522	23,930
		(16,898; 15,429)	(17,856; 16,196)	(18,890; 17,015)	(20,007; 17,890)	(21,215; 18,825)	(22,522; 19,813)	(23,930; 20,890)
	3.05	25,346	26,784	28,335	30,011	31,822	33,783	35,900
		(25,346; 23,143)	(26,784; 35,394)	(28,335; 25,522)	(30,011; 26,834)	(31,822; 28,238)	(33,783; 29,739)	(35,900; 31,340)
	4.06^g	33,795	35,712	37,780	40,014	42,430^h	45,044	47,870
		(33,795; 30,857)	(35,712; 32,391)	(37,780; 34,029)	(40,014; 35,779)	(42,430; 37,650)	(45,044; 39,653)	(47,870; 41,790)
	5.08	42,244	44,640	47,225	50,018	53,037	56,304	59,840
		(42,244; 38,572)	(44,640; 40,489)	(47,225; 42,536)	(50,018; 44,724)	(53,037; 47,063)	(56,304; 49,566)	(59,840; 52,240)
	6.09	50,693	53,568	56,670	60,022	63,645	67,565	71,810
		(50,693; 46,286)	(53,568; 48,587)	(56,670; 51,044)	(60,022; 53,669)	(63,645; 56,475)	(67,565; 59,479)	(71,810; 62,690)

^a The cumulative total represents the total number of HIV+ immigrants and those infected due to onward transmission living in the United States in year 20 due to the change of regulation. This number includes those immigrants who came in during year 20 as well as those living from previous years; this number also includes those cases due to onward transmission. This number excludes who died before year 20.

^b Year 20 represents the situation twenty years after the change in regulation, assuming that HIV+ immigrants seek treatment immediately upon arrival.

^c Average age of entry represents HIV+ immigrants' average age when entering the United States.

^d The onward transmission rate, per 100 HIV+ immigrants, is based on 0%, 25%, 50%, 75%, 100%, 125%, and 150% of the calculated onward transmission estimate (see note e).

^c This value is the weighted average of onward transmission cases due to sexual transmission in the United States (*Pinkerton SD. How many sexually-acquired HIV infections in the USA are due to acute-phase HIV transmission? AIDS. 2007 July 31; 21(12): 1625–1629.*).

^f The rate of HIV positive immigrants, per 100 immigrants to the United States is based on 25%, 50%, 75%, 100%, 125%, and 150% of the estimate for the prevalence all immigrants (see note g).

^g This is the calculated estimate for the rate of HIV positive immigrants; it is based on a weighted average of regional prevalence rates of HIV rates and estimates of immigration rates to the United States.

^h This is the result of using the calculated weighted average of prevalence of HIV (weighted by regional prevalence and immigration rate) and the weighted average of onward transmission in the United States (see notes e and g).

v) Limitations: The more prominent limitations of the HIVEcon model used to produce the results presented in this report are:

1) Estimated number and age of HIV-infected immigrants in the primary case analysis: Because we could not locate any data on the prevalence and demographic characteristics of HIV-infected applicants seeking entry into the U.S., the estimate of number of HIV-infected immigrants is calculated assuming that the number of HIV-infected immigrants from each region will be the same proportion of HIV-infected persons in that region. That is, if there are, for example, 5 HIV-infected persons per 1,000 persons in a region, then the proportion of HIV-infected immigrants among all immigrants from that region will be 5 HIV-infected persons per 1,000 immigrants.

There are several possible reasons as to why the proportion of HIV-infected immigrants could be less or more than the prevalence of HIV-infected persons in the region of origin. For example, the cost of adequate medical care in the U.S. may make HIV-infected individuals reluctant to immigrate to this country. With the increase in the availability of appropriate HIV treatments in many parts of

the world, adequate treatment is often cheaper outside of the U.S. Conversely, in regions or specific countries where appropriate treatment is less readily available, the portion of HIV-infected immigrants from those regions could be higher than the prevalence of HIV-infected persons in that region. We are seeking comments on these assumptions and data that would further allow us to refine our estimates.

We also do not have information on the number of HIV-infected immigrants who successfully obtained waivers, thus allowing us to estimate the number of HIV-infected immigrants in the baseline). We do know that the number is small. For example, in Fiscal Year 2007, Department of State reported that its consular officers found 746 immigrants ineligible for admission to the U.S. under the communicable disease grounds of INA 212(a)(1)(A)(i). Of those immigrants 327 overcame the initial finding. What portion of those who tested positive for HIV infection is unknown.

HIVEcon does show, with the lower and upper bound rates of HIV-infected immigrants per 1,000 immigrants, the impact of assuming different rates of HIV-infected immigrants to the U.S.

2) Estimated average age of HIV-infected immigrants upon their entry into the U.S.: As demonstrated in the results in Section 5, 6 and 7, the assumed average age of HIV-infected immigrants upon entry into the U.S. can greatly influence the calculated economic impact.

We do not know what the average age of HIV-infected immigrants upon entry (if the proposed regulation is enacted) would be. As stated earlier, a user can, with HIVEcon, readily explore the impact of different average age of entry of HIV-infected immigrants.

Cost analysis: Perspective: Due to data limitations, the model, HIVEcon, only examines the health care costs of the new regulations. We have only limited data on nonhealth care costs and utilization among immigrant groups in the U.S. We do not have data on health care payers and the proportion of HIV-infected immigrants receiving the appropriate standard of care. We conducted sensitivity analyses on the health care cost inputs and identified, but not quantified, other potential costs.

Cost Data

Annual cost of treating an HIV positive patient in the U.S.: In a model-based analysis, Schackman et al (8) projected the lifetime cost of current treatment for HIV infection in the United States. Their model input data were derived from the HIV Research Network, a consortium of primary care sites that specialize in the treatment of HIV infection (14,15). Their analysis focused on a cohort of HIV-infected individuals with a mean CD4 cell count of 310 cells/mm³ and projected a mean survival of 24.2 years after cohort initiation. The undiscounted lifetime costs (of comprehensive treatment per HIV-infected person was \$618,900 (8). Antiretroviral therapy accounted for 73% of the total cost, inpatient care accounted for 13%, and outpatient care accounted for 9%. The estimates also include an 8% additional cost for other medications related to antiretroviral therapy and opportunistic infection prophylaxis and therapy. We use their monthly estimate (8) of \$2,100, annualized to \$25,200. In our calculations, we discounted this annual cost at 3% and 7%. We have also varied this estimate in our sensitivity analysis. A user of HIVEcon can readily alter this estimate.

We did not include any other costs in our costs analysis. This is because, even if HIV-related health

restrictions are removed as a barrier to admission for immigrants, all immigrants still must meet other admission requirements. In the United States, under the Federal Personal Responsibility Work and Opportunity Reconciliation Act (PRWORA) of 1996, most immigrants are not eligible to receive means-tested public benefits for 5 years after their entry into the U.S. (16,17). Federal means-tested public benefits include Supplemental Security Income (SSI), cash Temporary Assistance for Needy Families (TANF), Medicaid, and food stamps (16,18). State and local means-tested benefits are determined at the state or local level and vary by jurisdiction. We have no data to assume that HIV-infected immigrants will seek, 5 years after being admitted to the U.S., such benefits at rates different from non HIV-infected immigrants.

In addition, PRWORA placed other limitations on aliens' access to public benefits, making them more difficult for aliens to obtain such benefits in the first place. For example, the income and resources of the sponsor of a family-based immigrant or permanent resident are deemed to be available to that alien if he/she should apply for certain means-tested public benefits. See 8 U.S.C. 1631, 1632. Since a sponsor must first prove to DHS

that he/ she is able to provide support to the sponsored alien at an annual income that is at least 125% above the federal poverty level before the alien's immigration application will be approved, it is unlikely that the alien will be able to show that his/ her available resources fall beneath the low income eligibility thresholds required for many means-tested public benefits. See INA, § 213A(a) (1) (A) .

We also have not included costs associated with decreased productivity due to illness associated with HIV infection in immigrants and in the persons to whom they transmit the infection. We have only limited data on income and employment of immigrant populations but no data on the impact of HIV infection.

Thus, beyond the costs of treatment for HIV and related conditions (and we include the costs of treating those U.S. persons who are infected due to onward transmission), we have not quantified costs that HIV-infected immigrants will incur within the U.S. We are seeking comment and additional data on such costs.

Cost analysis: Sensitivity analyses on costs: In addition to calculating the impact of different discount rates (3% and 7%), we also examined the impact of altering the costs of treatment and, simultaneously, the impact of altering the rates of onward transmission. Schackman et al (8) estimated cost assuming a 30% reduction costs of drugs (for example, due to "additional manufacturers rebate"). To illustrate the impact of altering the annual cost of treatment, we decreased and increased the annual cost of \$25,200 by +/- 30% (lower estimate of \$19,466; upper estimate of \$30,954)

Cost Results

i) Assuming immigrants have an average age of entry of 30 years, the primary case undiscounted cost (costs of treating HIV cases, see earlier) in the first year would be approximately \$98,414,278 (lower bound: \$24,713,774; upper bound: \$147,555,771) (see Table 1 for definitions of primary, lower and upper bounded cases. Costs estimated assuming 1.51% annual onward transmission rate). Discounted at 7%, the equivalent values are \$91,975,961 (lower bound: \$23,096,985; upper bound: \$137,902,590)

By year 20, this amount increases to \$952,060,384 (lower bound: \$239,081,220; upper bound: \$1,427,415,519) (undiscounted) (see Technical Appendix Table II.9a). Discounted at 7%, the equivalent values are \$246,030,495 (lower bound: \$61,783,130; upper bound: \$368,881,632).

In comparison, immigrants who have an average age of entry at 40 years would also have the same costs in year 1 (\$98,414,278). By year 20 post enactment of the regulation, however, the undiscounted costs of the immigrants aged 40 years upon entry amounts to \$857,534,372 (lower bound: \$215,343,866; upper bound: \$1,285,729,553) (see Technical Appendix Table II.9b).

ii) If we exclude onward transmission from the analysis, and assuming immigrants have an average age of entry of 30 years, the primary case undiscounted cost in the first year would be approximately \$96,950,328 (lower bound: \$24,346,148; upper bound: \$145,360,823) (see Technical Appendix Tables II.10 a, b, c). Discounted at 7%, the equivalent values are \$90,607,783 (lower bound: \$,22,752,409; upper bound: \$135,851,236). These costs represent 98.5% of the costs that include those due to onward transmission.

By year 20, this amount increases to \$851,634,314 (lower bound: \$213,862,245; upper bound: \$1,276,883,402) (undiscounted). Discounted at 7%, the equivalent values are \$220,078,490 (lower bound: \$55,266,068; upper bound: \$329,970,985). These costs represent approximately 89.5% of the costs that include those due to onward transmission. That is, by year 20, the costs associated with cases generated due to onward transmission represent approximately 10.5% of total costs (undiscounted).

iii) Sensitivity analysis; Impact of discounting, altering rate of onward transmission and average annual medical costs. Costs at year 20. In Table 4 we present the results of a three-way sensitivity analysis showing the impact of varying discount rates (0%, 3%, 7%), varying rates of onward transmission (0%, 1.51% and 3.2%), and three different annual costs of treatment (primary estimate of \$25,200, and then +/- 30%). The results were calculated assuming an annual rate of HIV positive immigrants of 4.06/1,000 immigrants.

Changing the annual cost of treatment has an obvious impact on the total costs, but the chosen rate of discounting has

the largest impact (Table 4). In this sensitivity analysis, changing the rate of onward transmission has the smallest impact. For a given cost of treatment, moving from 0% onward transmission to 3.02% onward transmission caused an increase of approximately 25.6%. But, discounting costs by even 3% per year caused an approximately 55% in costs.

Table 4: Cost analysis: Sensitivity Analysis. A comparison of the impact on costs of HIV-infected immigrants due to varying discount rates and: Costs at year 20

<i>Onward transmission</i>	<i>Average annual medical costs per patient</i>	<i>Annual Cost (undiscounted)</i>	<i>Annual Cost (discounted at 3%)</i>	<i>Annual Cost (discounted at 7%)</i>
0	\$19,466	\$657,853,713	\$364,237,650	\$170,001,900
	\$25,200	\$851,634,314	\$471,529,271	\$220,078,490
	\$30,954	\$1,046,090,816	\$579,195,121	\$270,329,745
1.51	\$19,466	\$735,428,867	\$407,189,132	\$190,048,794
	\$25,200	\$952,060,384	\$527,132,751	\$246,030,495
	\$30,954	\$1,169,447,505	\$647,494,730	\$302,207,458
3.02	\$19,466	\$825,940,019	\$457,302,963	\$213,438,596
	\$25,200	\$1,069,232,943	\$592,008,356	\$276,310,111
	\$30,954	\$1,313,374,465	\$727,183,597	\$339,400,920

Notes:

Average age of entry of HIV+ Immigrants to the United States assumed to be 30 years.

Results calculated assuming primary case of rate of HIV positive immigrants at 4.06 per 1,000 immigrants.

iv) Cumulative total costs: In Table 5 we present the results of the cumulative total cost of treating HIV positive immigrants plus those cases generated due to onward transmission (assumed to be 1.51%). By year 20, the cumulative, undiscounted costs will be \$12,712,564,650 (\$5,695,373,827 discounted at 7%).

Table 5: Cumulative total costs of treating HIV positive immigrants.

Year	Cumulative present value (undiscounted)	Cumulative present value (discounted at 3%)	Cumulative present value (discounted at 7%)
1	\$98,414,278	\$95,547,843	\$91,975,961
5	\$1,316,781,552	\$1,184,735,214	\$1,036,058,444
10	\$4,225,172,011	\$3,470,925,628	\$2,716,672,394
20	\$12,712,564,650	\$8,817,948,745	\$5,695,373,827
25	\$17,653,167,533	\$11,322,037,845	\$6,740,956,908
50	\$43,372,996,582	\$19,869,994,895	\$8,944,933,304

Notes:

Average age of entry of HIV+ Immigrants to the United States assumed to be 30 years.

Results calculated assuming primary case of rate of HIV positive immigrants at 4.06 per 1,000 immigrants.

Average annual medical costs set at \$25,200 (before discounting).

These results include an assumed annual onward transmission rate of 1.51%

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I. Technical Appendices

Technical Appendix I: Borse RHH, Meltzer MI. HIVEcon: A model to estimate the economic costs of immigrants who are HIV+. Available at: www.cdc.gov/ncidod/dq

Technical Appendix II: Borse RHH, Meltzer MI. Additional notes and data on inputs and outputs. Available at: www.cdc.gov/ncidod/dq

V. Regulatory Flexibility Analysis

HHS/CDC has considered the proposed rule's effects on small entities, as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq., Pub. L. 96-354) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121). The RFA establishes, as a principle of regulation, that agencies should tailor regulatory and informational requirements to the size of the entities, consistent with the objectives of a particular regulation and applicable statutes.

The objective of this analysis was to compare the benefits and the costs of a change in legislation that currently prohibits HIV-infected immigrants from entering the United States. HHS/CDC carefully considered several

other alternatives, but they were either not logistically feasible or inconsistent with current public health practice or appeared legally impermissible under applicable law. This analysis appears in the 'Alternatives' section.

HHS/CDC certifies the proposed rule will not have a significant impact on a substantial number of small entities as defined in the statute.

VI. Other Administrative Requirements

A. The Unfunded Mandates Reform Act

HHS/CDC evaluated the rule requirements for compliance with the Unfunded Mandates Reform Act (UMRA) of 1995. This rule does not contain Federal mandates under the regulatory provisions of Title II of the UMRA for State, local, or Tribal Governments, nor for the private sector. The rule's provisions will not affect small Governments.

B. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045 requires HHS/CDC to determine whether the rule is economically significant. The Executive Order further requires HHS to determine whether the rule would create an environmental health or safety

risk disproportionately affecting children. HHS/CDC has determined that this rule of general applicability is consistent with these principles.

C. Paperwork Reduction Act of 1995

The Paperwork Reduction Act applies to the data collection requirements found in 42 CFR part 34. Currently, aliens determined to have a communicable disease of public health significance may request a waiver from DHS to enter the United States under sections 212(d)(3)(a) and 212(g) of the INA (8 U.S.C. 1182(d)(3)(a) and 1182(g)). HHS/CDC has approval from the Office of Management and Budget (OMB) under OMB Control No. 0920-0006: Statements in Support of Application for Waiver of Inadmissibility under the Immigration and Nationality Act (expiration date December 31, 2011) to collect data pertaining to the waiver. CDC Form 4.422-1b is the form that is required in support of a waiver of inadmissibility for HIV infection. If the proposed change is finalized, infection with HIV would no longer be grounds for an alien to apply for a waiver and HHS/CDC would discontinue the use of CDC form 4.422-1b, for a reduction of 67 burden hours for this approved data collection.

D. Environmental Impact

HHS has determined that provisions to amend 42 CFR 34.2(b) will not have a significant impact on the human environment.

E. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, September 9, 2000), requires agencies to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." The Executive Order defines the phrase "policies that have tribal implications" to include regulations and other policy statements or actions that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes."

HHS/CDC has determined that provisions to amend 42 CFR Part 34 will not have tribal implications.

F. Executive Order 12630: Governmental Actions and Interference with Constitutionally Protected Property Rights

Under Executive Order 12630, if the contemplated rule would require a Federal taking of private property, then a takings analysis is required. Since the proposed rule does not require a Federal taking of private property, the provisions in the Executive Order are not applicable.

G. 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 determines that this proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

H. Executive Order 13211: Energy Effects

Executive Order 13211 requires HHS/CDC to produce a statement of energy effects if the proposed rule is significant or economically significant and likely to have a significant adverse effect on the supply, distribution, or use of energy. HHS/CDC has determined that the proposed rule does not have that effect and that a statement of energy is not required.

I. National Technology Transfer and Advancement Act

This act, 15 U.S.C. 272, requires the adoption of technical standards developed or adopted by voluntary consensus standards bodies in rules promulgated by HHS. No voluntary consensus standards are applicable and feasible with regard to the proposed rule.

J. Assessment of Federal Regulations and Policies on Families

Title 5 U.S.C.A. 601 (note) requires agencies to assess the impact of a proposed action to determine whether such an action would affect family well-being. HHS/CDC has assessed the impact of this proposed regulation and determines that it would not negatively affect family well-being.

K. Executive Order 12988: Civil Justice Reform

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

L. Plain Language in Government Writing

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 promulgating the proposed rule and would welcome any comment from the public in this regard.

List of Subjects in 42 CFR Part 34

Aliens, Health Care, Scope of Examination, Passports and Visas, Public Health

For the reasons stated in the preamble, the Centers for Disease Control and Prevention, within the U.S. Department of Health and Human Services, is proposing to amend 42 CFR part 34 as follows:

PART 34 - MEDICAL EXAMINATION OF ALIENS

1. The authority citation for Part 34 continues to read as follows:

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

§ 34.2 [Amended]

2. Amend § 34.2 by removing paragraph ((b)6) and redesignating paragraphs (b)(7) through (10) as (b)(6) through (9), respectively.

3. Amend § 34.3 by revising paragraphs (b)(1)(i), (e)(1) introductory text, (e)(2)(iii), (e)(2)(iv), (e)(5), and (e)(6) to read as follows:

§ 34.3 Scope of examinations.

* * * * *

(b) * * *

(1) * * *

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

* * * * *

(e) * * *

(1) As provided in paragraph (e)(2) of this section, a chest x-ray examination and serologic testing for syphilis shall be required as part of the examination of the following:

* * * * *

(2) * * *

(iii) For applicants 15 years of age and older, serologic testing for syphilis.

(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 x-ray 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 x-ray examination for good cause, upon application approved by the Director.

* * * * *

(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 (approximately 14 x 17 inches; 35.6 x 32.2 cm).

(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.

* * * * *

Dated: June 16, 2009.

Kathleen Sebelius
Secretary

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