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 Definition 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 revise the Part 34 regulation to remove ''Human Immunodeficiency Virus (HIV) infection'' from the definition of ''communicable disease of public health significance.'' HHS/CDC is also proposing to remove references to ''HIV'' from the scope of examinations in its regulations. Aliens infected with a ''communicable disease of public health significance'' are inadmissible into the United States under the Immigration and Nationality Act (INA).

The Tom Lantos and Henry Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (the July 2008 legislation reauthorizing the President's Emergency Plan for AIDS Relief (PEPFAR)) removed language from the INA which had previously mandated that HIV be on the list of diseases that can bar entry to the U.S. This legislative change allowed HHS/CDC to reassess whether HIV infection should be retained or removed from regulations based on sound public health science and current understanding of HIV epidemiology. There are other diseases, including sexually transmitted diseases, which CDC may remove from the definition of ''communicable disease of public health significance'' through future rulemaking after scientific review.

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. 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 and they would no longer undergo HIV testing as part of the routine medical examination.

DATES: Written comments must be received on or before August 17, 2009. Comments received after August 17, 2009 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, NE., MS E–03, Atlanta, Georgia 30333. You may also submit written comments electronically via the Internet at the following Address: *http://regulations.gov,* or via e-mail to *Part34HIVcomments@cdc.gov.*

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, NE., Atlanta, Georgia 30333. Please call ahead to 1–404–498–1600, and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit.

Comments will also be available for viewing at the following Internet address: http://www.cdc.gov//ncidod/dq. 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, NE., MS E–03, Atlanta, Georgia 30333; telephone 1–404–498–1600.

SUPPLEMENTARY INFORMATION:

The NPRM is organized as follows:

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

i. 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. 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, 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.

On October 6, 2008, HHS/CDC revised 42 CFR 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: active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, *lymphogranuloma venereum, granuloma inguinale,* and HIV infection; quarantinable diseases designated by Presidential Executive Order; and 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 of 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 Web site, located at the following Internet address: *http://www.cdc.gov/ncidod/dq/technica.htm.*

ii. Legislative and Regulatory History

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, Congress added HIV infection to the list of dangerous contagious diseases. Public Law 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, Public Law 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, Public Law 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, Public Law 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 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 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.

iii. Immigration to the U.S. and Relevant Visa Categories

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 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) 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 a qualified 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 Web site (*http://travel.state.gov*).

Aliens who are already in the United States may apply to adjust to permanent resident status pursuant to the family-based and employment-based categories described above, as well as several other statutorily-eligible adjustment categories. *See INA* section 245; 8 U.S.C. 1255. Refugees and aslyees may also apply to adjust to permanent resident status from inside the United States. *See INA* section 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 section 244; 8 U.S.C. 1255a; 8 CFR Part 244. TPS applicants are also subject to the medical grounds of inadmissibility. Currently, if a TPS applicant is infected with HIV, DHS requires that the applicant be granted a waiver of inadmissibility before TPS can be granted.

Section 101(a)(42)(A) of the INA generally defines refugees 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. An applicant is preliminarily approved for refugee status overseas, but is 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 section 207; 8 U.S.C. 1157; 8 CFR Part 207.

vi. Current Scientific Knowledge for HIV Transmission

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 as is the case with other serious conditions such as tuberculosis. An arriving alien with HIV infection does not pose a public health risk to the general population through casual contact.

CDC has determined that HIV infection is transmitted among individuals in the United States almost exclusively by the following mechanisms: Unprotected sexual intercourse with an HIV-infected person, sharing needles or syringes contaminated with HIV, and mother-to-child transmission of HIV 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. Interventions have been successful at mitigating exposure to and transmission of HIV.

v. Global Context

In 2004, the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the International Organization for Migration (IOM) issued the ''UNAIDS/IOM Statement on HIV/AIDS-related travel restrictions'' which provides guidance to governments regarding addressing the public health, economic, and human rights concerns involved in HIV-related travel restrictions. This document concludes that HIV-related travel restrictions have no public health justification.

There are a dozen countries that deny entry if a person has HIV. These countries are: Armenia, Brunei, Iraq, Libya, Moldova, Oman, Qatar, the Russian Federation, Saudi Arabia, South Korea, Sudan, and the United States.

This proposed rule will remove the United States from the list of countries that continue to have entry restrictions for HIV-infected individuals.

III. Summary of Proposed Changes to 42 CFR Part 34

This proposed rule removes HIV infection from the definition of *communicable diseases of public health significance* as defined in 42 CFR 34.2(b) and scope of examinations in 42 CFR 34.3.

Section 34.2(b) Communicable Diseases 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 human immunodeficiency virus (HIV) infection from the specific 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 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. Interventions have been successful at mitigating exposure to and transmission of HIV.

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.

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 disease 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 testing requirements for other health-related conditions which are not included in the current definition of *communicable disease of public health significance.* Therefore, HHS/CDC is proposing to remove the specific 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 may be an economically significant action under the Executive Order.

In the analysis that follows, we assess the potential impacts of removing HIV from the list of specific communicable disease 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. We are seeking comments on this preliminary regulatory impact analysis, including the identification of potential data sources that would allow us to more appropriately characterize and estimate the impact of the proposed rule.

A. Objectives and Basis for the Action

Prior to the enactment of the United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, HHS/CDC was required by statute to list HIV as a ''communicable disease of public health significance.'' Now that the statute provides discretion, 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, but to remove a government-imposed barrier that does not appear to provide a significant public health benefit and is at odds with human rights considerations.

B. 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, if eligible, 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. Currently, there are already roughly 1 million persons in the United States living with HIV [1]. Thus, maintaining HIV infection on the list of excludable conditions for entry into the U.S. would not result in significant 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 diseases 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 similar to an approach followed by some countries. Under this approach, all those aliens who test positive for HIV infection could be informed of their HIV status, counseled regarding their condition, the need for appropriate treatment, and the steps that should be taken to minimize the risk of onward transmission.

There are potential public health benefits to a mandatory testing approach. The medical examination offers a unique opportunity to both inform immigrants of their HIV status and link them with care. Through screening, HIV-infected aliens who are potentially unaware of their HIV status would become aware of their status and could be linked with prevention, care and treatment options in the United States. 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 [2, 3]. These public health benefits are the basis for the HHS/CDC's ''Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings,'' which states that the characteristics of HIV infection are consistent with all generally accepted criteria that justify voluntary screening [4]. However, mandatory HIV testing is limited to certain infrequent cases such as blood and organ donors.

There are also disadvantages to continued mandatory testing if HIV infection is removed from the definition of a *communicable disease of public health significance.* Mandatory testing for other serious health-related conditions that are not inadmissible health conditions, (*e.g.,* infectious diseases, such as hepatitis, malaria, and West Nile virus and chronic conditions such as diabetes and heart conditions), are not required as part of this medical examination. Thus, continued

mandatory HIV testing would differentiate HIV from other serious health-related conditions. Second, although the purpose of the medical examination is to identify health conditions considered inadmissible on public health grounds, the results of exams conducted by panel physicians in the immigrant's home country might not be kept confidential because of requirements in the country of origin making it necessary to report HIV results to local authorities. DHS would also know an applicant's HIV status (while not necessarily other serious health conditions) due to this information being included on medical notification form and could be used by DHS in evaluating the possibility of the alien becoming a public charge. 42 CFR 34.3(b)(ii)(5). These results may be counter to HHS/CDC objectives of reflecting current scientific knowledge and public health best practices, and reducing stigmatization of and discrimination against people who are HIV-infected. Therefore, as discussed below in the 3rd approach, HIV testing, consistent with CDC's recommendations for general screening, would be available.

Although the approach of removing HIV from the definition of *communicable disease of public health significance* but maintaining the mandatory testing component of the medical examination was not selected for this proposal, HHS/CDC welcomes public comment on the advantages and disadvantages of this or alternative approaches, such as (non-mandatory) testing (*i.e.,* opt out/opt in approach).

3. The third approach is to remove HIV infection from the definition 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 of admissibility. This is the regulatory approach that HHS/CDC selected. Along with this approach, all immigrants, refugees and status adjusters would still have the opportunity to receive information about HIV testing and to be tested in the United States as recommended by the CDC guidelines [4]. The discussion of the potential impacts of the rule that follow relate to this approach.

C. Baseline and Incremental Analysis

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 currently 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 explicitly included refugees and TPS-turned permanent residents in our analysis, 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 is not likely to 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.

Furthermore, though this policy would increase the total number of people who may be eligible to be admitted, we assume that the total number of immigrants who are annually admitted into the United States is fixed over time. Thus, the incremental input to the rule is a calculation of the additional costs due to HIV-infected immigrants above the costs of non-HIV-infected immigrants. In general, given that the total number of immigrants is not likely to change and the share of HIV-infected immigrants is likely to be relatively small, the rule will not likely have an appreciable impact on the economy in terms of wages, productivity, or prices of goods and services.

D. Defining the Population Affected

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. The proposed changes in the medical examination of aliens regulations affect all foreign nationals entering 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 currently required to request waivers to obtain entrance. If this rule is finalized, that waiver process will no longer be necessary. Data on the number of waivers granted annually based on HIV status are not available but costs to obtain waivers are thought to be minimal. For example, in Fiscal Year 2007, the 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. This analysis is limited to aliens seeking to become lawful permanent residents who are required to have a medical examination to determine admissibility. Because visitors, refugees and TPS applicants have historically had the option of obtaining a waiver to enter and remain in the U.S., these groups are not included in this analysis.

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, we estimate 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 (see Table 1 for the summary of regional estimates and weights and Technical Appendix II, Table 1: Summary of Model, HIVEcon, Inputs and Assumptions for Primary, Lower and Upper Bound Analyses [5]).

TABLE 1—REGIONAL POPULATION, IMMIGRATION AND HIV ESTIMATES USED TO CALCULATE THE WEIGHTED REGIONAL RATE ESTIMATES

	Legal permanent residents (2007) [6]	Estimate of HIV rate per 1,000 (based on 2006 regional population estimates [7] and 2007 HIV regional estimates [8])			Estimated number of HIV infected immigrants		
		Primary	Low	High	Primary	Low	High
Africa*	96,105	18.05	16.70	19.57	1,735	1,605	1,880
Asia	383,508	1.29	1.05	1.63	494	403	624
Europe	120,821	3.23	2.46	4.38	390	297	529
N. America	339,355	3.84	1.42	5.61	1,302	481	1,903
Oceania	6,101	2.19	1.55	3.50	13	9	21
S. America	106,525	3.20	2.81	3.79	341	300	404
Total	1,052,415	4.98	4.35	5.73	.....	.....	.....
HIV positive Rate per 1,000 U.S. immigrants †		4.06	‡ *2.94*	‡ *5.09*	4,275	*3,096*	*5,361*

* In this case, Africa includes North Africa, the Middle East and Unknowns.

** Total number of adults and children living with HIV in the region *(see Technical Appendix II for more detail [5]).*

† Based on weighted regional estimates. The assumption is that prevalence of HIV amongst immigrants to the U.S. mirrors that of the immigrant's native regions and is adjusted for the number of immigrants coming to the U.S. from each region.

‡ Note: These estimates represent the 5th and 95th percentiles based on regional weight estimates. Due to concern that immigrants may not be representative of the typcial country level estimates and thus may be outside the confidence interval, for purposes of this analyses we expanded our confidence interval to 25% to 150% of the Primary estimate (*i.e.* 1.02 to 6.09 HIV+ immigrants per 1,000 immigrants).

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)[8]. HHS/CDC used regional data and rates that 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 [7]. After examining the immigration data, by region, from the *Yearbook of Immigration Statistics: 2007 Immigrants [6],* we assigned regional weights according to the number of aliens coming to the United States from each region.

The 2007 Immigration Statistics [6, 9] indicate that 1,052,415 persons became permanent residents in 2007. Multiplying this number by our prevalence estimate of 4.06 HIV-infected immigrants per 1000 immigrants yields an estimated 4,275 HIV-infected immigrants who would enter into the United States each year.

However, we note that there are significant uncertainties in this estimate since no specific data exist on the HIV prevalence of persons seeking to immigrate to the United States. We do not have a basis to judge whether these immigrants who qualify for permanent residence differ from the general regional population in terms of HIV prevalence; thus, for the purposes of this analysis 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.

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.

However, we also conducted sensitivity analyses to assess the impact of altering this assumption. We used a range of 1.02 to 6.09 HIV-infected persons per 1,000 immigrants based on 25% and 150% of the mean weighted average, 4.06 per 1,000 immigrants (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 U.S. in 2007. This range yields a lower bound estimate of 1,073 and an upper bound estimate of 6,409 HIV-infected persons entering the United States annually (see Technical Appendix II [5]). Because the impact of the proposed rule change is highly sensitive to HIV prevalence in aliens entering the U.S., we are seeking comment on these assumptions.

E. Benefits

HHS/CDC is proposing to remove HIV infection from the definition of *communicable disease of public health significance* contained in 42 CFR 34.2(b) and scope of examination, 42 CFR 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.

The benefits from this action are difficult to quantify. Based on the estimate above, this rule would allow perhaps roughly 4,000 persons to enter the United States annually who are otherwise admissible but are denied admission solely based on their HIV status. The rule will bring family members together who had been barred from entry, thus strengthening families. Also, HIV-infected immigrants with skills in high demand would be permitted to enter the U.S. to seek employment and contribute as productive members of U.S. society. 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. These HIV-infected individuals, compared to those who do not receive appropriate multi-drug anti-retroviral therapy for HIV treatment, could survive an additional 13 years, with an average life expectancy of approximately 29 years (to age 49 years) [10]. This increased life expectancy allows the opportunity for longer and improved productivity.

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 who have long been denied entry into the U.S. based only on a treatable and preventable medical condition. This proposed rule will bring the U.S. in line with current science and international standards of public health and human rights practice.

Though this rule is assumed to not have an impact on the total number immigrants annually admitted as legal permanent residents, we note that immigration, in general, produces net economic gains for the United States. Overall, an NRC study estimated that immigrants, in general, create an annual economic impact of between $1 billion to $10 billion [11].

HHS/CDC welcomes comments on these and other benefits associated with the proposed regulatory change.

F. Costs

To the extent the proposed rule will result in an increased number of HIV-infected immigrants to the U.S. each year, there will be quantifiable impacts. We have made our best attempt to capture the likely effects of the rule, but there are significant uncertainties in this estimation effort. HHS/CDC encourages public comment on costs associated with this rulemaking and, in particular, additional information that would provide a basis for more robust qualitative discussion or quantitative estimates.

Impact on Health Care Expenditures

As previously discussed, the incremental impacts of the rule should be a comparison between the arrival of an HIV-infected immigrant and the arrival of an HIV-negative immigrant. Presumably, HIV-related healthcare expenditures will be different, but there are a variety of health expenditures that the HIV-infected immigrant may not incur that other immigrants may incur (*e.g.,* certain types of cancer, diabetes, heart disease). It is not clear that, over the course of a lifetime, on net an HIV-infected immigrant would consume more health care resources than other immigrants. Furthermore, HIV treatment yields benefits that offset the expenditures, including increased life expectancy and productivity.

However, given that health care expenditures associated with treatment of HIV infection can be substantial and may result in some fiscal impacts (as discussed below), we developed a model (HIVEcon) to estimate these potential effects of the rule. A complete description of the model including assumptions, results and limitations is available for comment [5]. The spreadsheet model itself is also available for download so that the reader can determine the relative impact of altering almost any input value, individually or several simultaneously [12].

The model, HIVEcon, examines the treatment costs as estimated by Schackman *et al.* [13] associated with newly identified persons infected with HIV regardless of payer, following the 2004 standards of care. The annual treatment cost is estimated to be $25,200 in 2004 dollars, with a range of $19,466 to $30,954. However, significant advances in the treatment of HIV have been made since 2004 [14], and are likely to continue to be made. Thus, the expenditure estimates could be an underestimate since as treatment options increase, the benefits such as quality of life and lifespan will increase but so will costs. However, these expenditures may be overestimates since it is not clear to what extent immigrants will seek and receive even the 2004 standard of care.

Therefore, assuming 0% onwards transmission from HIV-infected immigrants entering at an average age of 20 years, an average annual medical expenditures of $25,200 annually, an HIV prevalence rate among immigrants of 4.06 per 1,000, and a 3% annual discount rate, the primary estimate of the present value of lifetime medical costs for persons identified as HIV-infected in Year One is $94 million in the first year. The absolute lower bound estimate is $19 million in the first year (decreasing the prevalence rate to 1.02 HIV+ immigrants per 1,000 immigrants and the average annual medical expenditures to $19,466). The maximum upper bound estimate is $173 million (increasing the prevalence rate to 6.09 HIV+ immigrants among 1,000 immigrants, and the average annual medical expenses to $30,954 per immigrant). In the HIVEcon model, in Year Two following the change in regulations, as the cumulative number of HIV-infected immigrants almost doubles, so will these health expenditures. Likewise in the third year, the expenditures will be equivalent to three years' worth of immigrants (excluding those who have passed away) and so on until the HIV-infected immigrants reach their life expectancy (*e.g.,* in the model, an HIV-infected person at age 30 has an average life expectancy of 24.7 years).

Comparison With Congressional Budget Office Analysis

The Congressional Budget Office (CBO) estimated the cost to the federal government of Section 305 of PL 110–293 prior to the law's enactment. The analysis included increases in direct spending related to provision of health care and other benefits paid for by the federal government. Specifically, those benefits include Medicaid, Supplemental Security Income, Food Stamps, and nutritional programs. In total, CBO estimated that providing these benefits to HIV-infected immigrants and their citizen children will increase spending by less than $500,000 in 2010 and $83 million over the 2010–2018 period, primarily for Medicaid.

The CBO analysis was done for the purpose of estimating the impact of PL 110–293 on the federal budget. This analysis was done to comply with Executive Order 12866, which directs agencies to assess all costs of available regulatory alternatives, including, but not limited to, those costs incurred by the federal government. The economic analysis for this regulation differs from the CBO analysis for PL 110–293 in four major areas: (1) The CBO analysis assumed that the HIV prevalence rate would be equal to half of the weighted-average HIV prevalence rate for the immigrants' country of origin, whereas this analysis assumed that the HIV prevalence rate would be equal to the weighted-average rate of the immigrants' region of origin; (2) the number of immigrants was increased by 5% each year in the CBO analysis while this analysis did not include growth in the annual number; (3) the CBO analysis only examined health care costs paid for by Medicaid whereas this analysis included all health care costs including those paid for by the Ryan White Program; and (4) the CBO analysis included costs of federal disability and nutrition benefits, whereas this analysis did not include those costs.

By the year 2013, the number of HIV-infected immigrants entering the U.S. projected by the CBO analysis is roughly equivalent to that projected by this

analysis (analytical differences in prevalence and growth rates cancel out). By 2018, the number of HIV-infected immigrants projected by the CBO analysis exceeds projections in this analysis. The health care costs in this analysis exceed that of CBO's analysis because the former included all federal and nonfederal costs including those costs paid for through the federally-funded Ryan White Program. This analysis did not include non-healthcare costs.

We are seeking comments on these assumptions and data that would further allow us to refine our estimates. We welcome comment on the estimated prevalence of HIV among those likely to immigrate based on, for example, humanitarian waivers or other sources of available data.

Potential Fiscal Impacts

As previously discussed, 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 five years after their entry into the U.S. [15, 16]. Federal means-tested public benefits include Supplemental Security Income (SSI), cash Temporary Assistance for Needy Families (TANF), Medicaid, and food stamps [15, 17]. 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, five 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).

However, some immigrants may be eligible for certain assistance through the Ryan White HIV/AIDS Program—a federally-funded program that provides HIV-related health services. Funds are awarded to agencies located around the country, which in turn deliver care to eligible individuals. Since the program is administered through different grantees using different eligibility criteria, it is difficult to assess to what extent the HIV-infected immigrants will be eligible for assistance through this program. However, given that the estimated number of new HIV-infected immigrants entering the United States as a result of this rule are relatively small (around 4,000 annually) compared to the total number of persons currently assisted by the funding (roughly half a million), the overall impact on the program is likely small.

Onward Transmission

Though difficult to quantify with precision, there will likely be some additional cases of HIV due to onward transmission from HIV-infected immigrants to others in the United States who are not currently infected. The costs associated with onward transmission include:

- Shortened lifespan and reduction in quality of life even with treatment,
- The health care costs associated with treating HIV infection,
- The costs of social services when individuals are unable to fully support themselves because of their illness, and
- Decreased productivity when individuals become too sick to work.

Because health care costs are substantial and other costs listed above are difficult to quantify, the analysis in the HIVEcon model is limited to health care costs associated with treatment of HIV infection.

In the model, the number of estimated HIV-infected cases due to onward transmission (in Year t) is calculated as: [(Number of HIV-infected immigrants entering in Year t + Number of HIV-infected immigrants surviving from previous years that survive to Year t + additional persons previously infected by onward transmission from HIV-infected immigrants that survive to Year t) × onward transmission rate].

A 1.51% onward transmission rate was used in the HIVEcon model 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, when limited to sexual transmission, in the United States is 3.02 per 100 HIV positive immigrants [18]. In 2006, the overall rate for onward transmission of HIV in the U.S. from all causes, was 5 new infections per 100 HIV-infected persons [19]. Results from published research indicate that immigrants to the United States, regardless of their race or ethnicity, often have an initial better health profile than native-born Americans across diverse health behaviors and outcomes; however, this health advantage declines as length of residence in the United States and degree of acculturation increase [20–26]. Specifically, studies of HIV risk behavior among immigrant populations, upon arrival in the U.S., indicate that these behaviors are influenced by a number of factors including the demographic characteristics of the migrants (especially sex, social class, relationship status and education); the purpose of immigration; the type and location of their receiving community and the existing supports; discrepancy between pre-immigration expectations and post-immigration experiences; and transnational movement between the U.S. and their home countries [27–31]. These multiple factors result in heterogeneity in HIV risk between migrant communities, with some being at lower, and others higher risk, than their U.S. counterparts. There is no evidence to suggest immigration to the U.S. significantly affects HIV incidence in this country in one direction or the other. Thus, it is not unreasonable to assume that onward transmission rates amongst HIV-infected immigrants will be lower than among HIV-infected persons born in the U.S.

For this analysis, we assumed that the onward transmission rate for immigrants, and those that they infect, would be fifty percent of the average U.S. rate for sexual transmission (*i.e.,* rate of onward transmission from HIV-infected immigrants is assumed, in the baseline case, to be 1.51 per 100). Because data supporting this assumption are limited, this assumption was tested in sensitivity analysis. We used 0% transmission as our lower bound estimate and a transmission rate of 4.53 per 100 HIV-infected immigrants, and those that they infect, 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%.

Assuming 4,275 HIV-infected immigrants enter in the first year, there will be 65 new HIV infections due to onward transmission, assuming an

onward transmission rate of 1.51 per 100 HIV, with a range of 0 to 261 (assuming onward transmission of 0 and 4.53 per 100 HIV-infected immigrants, respectively). These estimates imply treatment costs, for those infected via onward transmission only, in the first year of $1.6 million in the primary estimate and a range of $0 to $8.1 million [5].

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. Thus, in the next year, though the cumulative number of HIV-infected immigrants essentially doubles, the number of new HIV cases (as well as the associated treatment costs) will be slightly more than double the previous year.

This modeling approach assumes that those people infected by HIV-infected immigrants would never have become infected with HIV were it not for the arrival in the U.S. of HIV-infected immigrants. This could be unrealistic since U.S. persons who are infected by HIV-infected immigrants may engage in behaviors that lead them to activities that expose them to HIV infections, regardless of the source of infection. An alternative interpretation may be that at least some of the additional infections are occurring earlier than they otherwise would have. Thus, these shifts in the timing of infection will increase the total number of new cases in any one year, but the true incremental impact may be the implications of becoming infected earlier.

Furthermore, the model treats the onward transmission rate as fixed over time. However, data shows that onward transmission has declined over time [19]. If we assume that transmission rates will continue to decrease in the future, it is possible that the model may overestimate the number of HIV-infected individuals due to onward transmission as we project impacts into the future.

G. Summary of Impacts

The HIVEcon model projects potential impacts out to 50 years after the rules go into effect. However, many of the key inputs to the model may be significantly different even ten years from now given the rapid pace of change in HIV treatment, HIV prevalence in other countries, as well as potential changes in the overall immigration policy. It may not be inconceivable that there would be an HIV vaccine in the next decade or two. Given these uncertainties, Table 2 provides a summary of the potential effects of the rule five years after implementation.

TABLE 2—SUMMARY OF IMPACTS (YEAR FIVE AFTER IMPLEMENTATION), ASSUMING THE AVERAGE AGE OF ENTRY IS 30 YEARS AND THE ANNUAL DISCOUNT RATE IS 3%

Category	Primary Estimate (4.06 HIV+ immigrants per 1,000 immigrants)	Low Estimate (1.02 HIV+ immigrants per 1,000 immigrants)	High Estimate (6.09 HIV+ immigrants per 1,000 immigrants)
HIV-POSITIVE IMMIGRANTS AT YEAR 5 (EXCLUDING ONWARD TRANSMISSION)			
Total number of HIV-Positive Immigrants present in the U.S	15,755	3,956	23,622.
Annualized Monetized Healthcare Expenditures	$342 million	$86 million	$513 million.
Benefits (Qualitative)	1. Reduce stigmatization of and discrimination against HIV-infected people. 2. Compared to those who don't receive appropriate multi-drug anti-retroviral therapy, survive an additional 13 years, with an average life expectancy of approximately 29 years (to age 49 years) [10]. This increased life expectancy allows opportunity for longer and improved productivity.		
HIV-POSITIVE CASES AT YEAR 5 DUE TO 1.51% ONWARD TRANSMISSION			
Total number of HIV-Positive cases due to 1.51% onward transmission connected with U.S. Immigrants.	676	170	1,014.
Annualized Monetized Healthcare Expenditures	$96 million	$24 million	$145 million.
TRANSFERS			
Federal Annualized Monetized	Depends upon assumptions of who pays annualized monetized medical costs.		

Notes: Source of estimates—see Figures 1, 3, and 4 in Technical Appendix II [5].

In the context of the U.S. HIV/AIDS prevalence, currently estimated at roughly 1 million persons [1] the 4,275 HIV-infected immigrants represents only 0.4% of the national total of persons living with HIV/AIDS. In the context of the new U.S. incidence of HIV, currently estimated at roughly 56,000 [32], the onward transmission of 272 by year five represents only 0.5% of the new cases.

In the primary estimate, the monetized costs, mainly the treatment cost of the onward transmission cases are relatively modest. In terms of health care expenditures for immigrants, by Year Five there will be a cumulative total of 15,755 HIV-infected immigrants living in the U.S., with another 676 cases occurring due to onward transmission (total: 16,431) (Table 2) These cases will incur $438 million of medical expenses in Year Five.

We conclude that while we do not believe HIV is a ''communicable disease of public health significance'' for the purposes of admissibility determinations, the rule may be

economically significant. However, due to all of the uncertainties previously discussed, we solicit comments on this tentative conclusion.

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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. 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 part 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 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, proposes 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) (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.

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Dated: June 30, 2009.

Kathleen Sebelius,

Secretary.

[FR Doc. E9–15814 Filed 6–30–09; 4:15 pm]

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