

Priority Mail Contract 16 (MC2009–36 and CP2009–55)
 Priority Mail Contract 17 (MC2009–37 and CP2009–56)
 Priority Mail Contract 18 (MC2009–42 and CP2009–63)
 Priority Mail Contract 19 (MC2010–1 and CP2010–1)

Outbound International
 Direct Entry Parcels Contracts
 Direct Entry Parcels 1 (MC2009–26 and CP2009–36)
 Global Direct Contracts (MC2009–9, CP2009–10, and CP2009–11)
 Global Expedited Package Services (GEPS) Contracts
 GEPS 1 (CP2008–5, CP2008–11, CP2008–12, and CP2008–13, CP2008–18, CP2008–19, CP2008–20, CP2008–21, CP2008–22, CP2008–23, and CP2008–24)
 Global Expedited Package Services 2 (CP2009–50)
 Global Plus Contracts
 Global Plus 1 (CP2008–8, CP2008–46 and CP2009–47)
 Global Plus 2 (MC2008–7, CP2008–48 and CP2008–49)

Inbound International
 Inbound Direct Entry Contracts with Foreign Postal Administrations
 Inbound Direct Entry Contracts with Foreign Postal Administrations (MC2008–6, CP2008–14 and MC2008–15)
 Inbound Direct Entry Contracts with Foreign Postal Administrations 1 (MC2008–6 and CP2009–62)
 International Business Reply Service Competitive Contract 1 (MC2009–14 and CP2009–20)

Competitive Product Descriptions
 Express Mail
 [Reserved for Group Description]
 Express Mail
 [Reserved for Product Description]
 Outbound International Expedited Services
 [Reserved for Product Description]
 Inbound International Expedited Services
 [Reserved for Product Description]
 Priority
 [Reserved for Product Description]
 Priority Mail
 [Reserved for Product Description]
 Outbound Priority Mail International
 [Reserved for Product Description]
 Inbound Air Parcel Post
 [Reserved for Product Description]
 Parcel Select
 [Reserved for Group Description]
 Parcel Return Service
 [Reserved for Group Description]
 International
 [Reserved for Group Description]
 International Priority Airlift (IPA)
 [Reserved for Product Description]
 International Surface Airlift (ISAL)
 [Reserved for Product Description]
 International Direct Sacks—M—Bags
 [Reserved for Product Description]
 Global Customized Shipping Services
 [Reserved for Product Description]
 International Money Transfer Service
 [Reserved for Product Description]
 Inbound Surface Parcel Post (at non-UPU rates)
 [Reserved for Product Description]

International Ancillary Services
 [Reserved for Product Description]
 International Certificate of Mailing
 [Reserved for Product Description]
 International Registered Mail
 [Reserved for Product Description]
 International Return Receipt
 [Reserved for Product Description]
 International Restricted Delivery
 [Reserved for Product Description]
 International Insurance
 [Reserved for Product Description]
 Negotiated Service Agreements
 [Reserved for Group Description]
 Domestic
 [Reserved for Product Description]
 Outbound International
 [Reserved for Group Description]

Part C—Glossary of Terms and Conditions
 [Reserved]

Part D—Country Price Lists for International Mail
 [Reserved]

[FR Doc. E9–26271 Filed 10–30–09; 8:45 am]

BILLING CODE 7710–FW–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 34

[Docket No. CDC–2009–0003]

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: Final rule.

SUMMARY: Through this final rule, the Centers for Disease Control and Prevention (CDC), within the U.S. Department of Health and Human Services (HHS), is amending its regulations to remove “Human Immunodeficiency Virus (HIV) infection” from the definition of *communicable disease of public health significance* and remove references to “HIV” from the scope of examinations for aliens.

Prior to this final rule, aliens with HIV infection were considered to have a *communicable disease of public health significance* and were thus inadmissible to the United States per the Immigration and Nationality Act (INA). While HIV infection is a serious health condition, it is not a communicable disease that is a significant public health risk for

introduction, transmission, and spread to the U.S. population through casual contact. As a result of this final rule, aliens will no longer be inadmissible into the United States based solely on the ground they are infected with HIV, and they will not be required to undergo HIV testing as part of the required medical examination for U.S. immigration.

DATES: This final rule is effective January 4, 2010.

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 404–498–1600.

SUPPLEMENTARY INFORMATION: The preamble to this final rule is organized as follows:

- I. Legal Authority
- II. Background
 - A. Medical Examination and Inadmissibility
 - B. Legislative and Regulatory History
 - C. Classes of Immigrants for Whom the Regulation Applies
 - D. Global Context
- III. Summary of NPRM
- IV. Relation of this Final Rule to the July 2, 2009, Notice of Proposed Rulemaking
- V. Overview of Public Comments
 - A. Comments on Removing HIV Infection From the Definition of *Communicable Disease of Public Health Significance*
 - B. Comments on Removing HIV Testing From the Scope of Examinations
 - C. Comments on the Economic Impact Analysis (EIA)
 1. General Comments on the Cost Analysis
 2. Comments on a Technical Review of the EIA
 - D. Comments on Technical Correction
- VI. Conclusions and the Final Rule
- VII. Required Regulatory Analyses Under Executive Order 12866
 - A. Objectives and Basis for the Action
 - B. Alternatives
 - C. Baseline and Incremental Analysis
 - D. Defining the Population Affected
 - E. Analysis of Impacts
 1. Potential Benefits
 2. Impact on Health Care Expenditures
 3. Comparison With Congressional Budget Office Analysis
 4. Potential Fiscal Impacts
 5. Onward Transmission
 - F. Summary of Impacts
 - G. Literature Cited
- VIII. Final Regulatory Flexibility Analysis
- IX. Other Administrative Requirements
 - A. The Unfunded Mandates Reform Act
 - B. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
 - C. Paperwork Reduction Act of 1995
 - D. Environmental Assessment
 - E. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

- F. Executive Order 12630: Governmental Actions and Interference With Constitutionally Protected Property Rights
- G. Executive Order 13132: Federalism
- H. Executive Order 13211: Energy Effects
- I. National Technology Transfer and Advancement Act
- J. *Assessment of Federal Regulations and Policies on Families*
- K. Executive Order 12988: Civil Justice Reform
- L. Plain Language in Government Writing

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

A. Medical Examination and Inadmissibility

Under section 212(a)(1) of the INA (8 U.S.C. 1182(a)(1)), any alien who is determined to have a *communicable disease of public health significance* is inadmissible to the United States. As a result of this statute, aliens outside the United States who have a *communicable disease of public health significance* are ineligible to receive a visa for admission into the United States, absent the grant of a waiver on the ground of inadmissibility. The grounds of inadmissibility also apply to most aliens who reside in the United States and are seeking adjustment of their status to that of a lawful permanent resident.

The Secretary of Health and Human Services (HHS) is authorized to promulgate regulations establishing the requirements for the medical examination of aliens by sections 212(a)(1) and 232 of the Immigration and Nationality Act (INA), and section 325 of the Public Health Service Act (42 U.S.C. 252). The regulations, administered by HHS/CDC, are promulgated at 42 CFR part 34.

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

Examination of Aliens, including the most current updates, that panel physicians and civil surgeons must follow in accordance with these regulations, are available to the public on the CDC Web site, located at the following Internet address: <http://www.cdc.gov/ncidod/dq/technica.htm>.

B. Legislative and Regulatory History

Beginning in 1952, the language of the INA mandated that aliens “who are afflicted with any dangerous contagious disease” are ineligible to receive a visa and therefore are excluded from admission into the United States. In April 1986, prior to the recent developments in medicine and epidemiologic principles concerning HIV infection, HHS published a proposal in the **Federal Register** to include *acquired immunodeficiency syndrome (AIDS)* as a dangerous contagious disease. See 51 FR 15354 (April 23, 1986). In June 1987, HHS published a final rule adopting this proposal. See 52 FR 21532 (June 8, 1987). Also during this time, HHS separately published a proposed rule to substitute HIV infection for AIDS on the list of dangerous contagious diseases. See 52 FR 21607 (June 8, 1987). While this proposed rule was pending public comment, Congress added HIV infection to the list of dangerous contagious diseases. Pub. L. 100–71, section 518, 101 Stat. 475 (July 11, 1987). In response to the congressional mandate, HHS issued final regulations to that effect in August of that year. See 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. 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. See 56 FR 2484 (January 23, 1991). Based on public comments received on this proposal, and after reconsideration of the issues, HHS published an interim final rule retaining all diseases on the list, including HIV infection, and

committed its initial proposal for further study. See 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 summer 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 infection 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. 110–293, section 305, 122 Stat. 2963 (July 30, 2008)].

In a separate action on October 6, 2008, HHS/CDC published an Interim Final Rule (IFR) announcing a revised definition of *communicable disease of public health significance* and revised scope of the medical examination in 42 CFR part 34. This IFR addressed concerns regarding emerging and reemerging diseases in immigrant and refugee populations who are bound for the United States. See 73 FR 58047 and 73 FR 62210. With the revision to 42 CFR Part 34, the definition of *communicable disease of public health significance* was modified to include two disease categories: (1) Quarantinable diseases designated by Presidential Executive Order; and (2) a communicable disease that may pose a public health emergency of international concern in accordance with the International Health Regulations of 2005, provided the disease meets specified criteria. Specific illnesses remaining as a *communicable disease of public health significance* were active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, lymphogranuloma venereum, granuloma inguinale, and HIV infection.

In response to the 2008 amendment to the INA, on July 2, 2009, HHS/CDC published a Notice of Proposed Rule Making (NPRM), which proposed two regulatory changes: (1) The removal of HIV infection from the definition of *communicable disease of public health significance*; and (2) removal of

references to serologic testing for HIV from the scope of examinations.

C. Classes of Immigrants for Whom the Regulation Applies

The provisions in 42 CFR part 34 apply to the medical examination of (1) aliens outside the United States who are applying for a visa at an embassy or consulate of the United States; (2) aliens arriving in the United States; 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.

Aliens who are already in the United States may apply to adjust to permanent resident status pursuant to statutorily-eligible adjustment categories. See INA § 245; 8 U.S.C. 1255. Refugees and asylees may 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 visa or asylee status, or through an adjustment of status must undergo a medical examination to determine whether the alien is inadmissible on medical grounds. Aliens seeking admission as refugees also undergo medical examinations overseas. 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 within DHS.

D. 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" that provides guidance to governments in regard to 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.

III. Summary of NPRM

On July 2, 2009, HHS/CDC published a notice of proposed rulemaking (NPRM) to remove HIV infection from the definition of *communicable disease of public health significance*, as defined in 42 CFR 34.2(b) and from the scope of examinations in 42 CFR 34.3. See 74 FR 31798.

Section 34.2(b) Communicable Diseases of Public Health Significance

Until this final rule, human immunodeficiency virus (HIV) infection was among those diseases listed in the definition of *communicable disease of public health significance*, as defined in 42 CFR part 34.2(b). As described in the "Legislative and Regulatory History" section above, 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 infection should remain in the definition of *communicable disease of public health significance* provided for in 42 CFR 34.2(b). In consideration of scientific evidence, including epidemiologic principles and current medical knowledge regarding the mode of HIV transmission, HHS/CDC proposed to remove HIV infection from the definition of *communicable disease of public health significance*.

Section 34.3 Scope of Examinations

HHS/CDC also proposed 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 definition of *communicable disease of public health significance* and directly relates to the diseases listed in Section 34.2(b) of 42 CFR part 34. It does not provide specific testing requirements for other health-related conditions that are not included in the current definition of *communicable disease of public health significance*.

Therefore, HHS/CDC proposed to remove the specific testing requirements for HIV infection in 42 CFR 34.3.

IV. Relation of This Final Rule to the July 2, 2009, Notice of Proposed Rulemaking

Through this final rule, HHS/CDC is now removing HIV infection from the definition of *communicable disease of public health significance* and from the scope of examinations. HHS/CDC received over 20,000 public comments on the NPRM, with the vast majority of commenters in support of the proposed changes, as written. HHS/CDC's evaluation of the comments did not lead to changes between the NPRM and this final rule. While HIV infection is a serious health condition, scientific evidence shows that it does not represent a communicable disease that is a significant risk for introduction, transmission, and spread to the United States population through casual contact. An arriving alien with HIV infection—or one adjusting status to that of a legal permanent resident—does not pose a public health risk to the general population through casual contact.

Beginning on the effective date of this final rule, HIV infection will no longer be an inadmissible condition, and HIV testing will no longer be required, for those aliens who are required to undergo a medical examination for U.S. immigration purposes.

The specific illnesses that are now listed in the definition of *communicable disease of public health significance* are: Active tuberculosis, infectious syphilis, gonorrhea, infectious leprosy, chancroid, lymphogranuloma venereum, and granuloma inguinale. The definition of *communicable disease of public health significance* also consists of (1) quarantinable diseases designated by Presidential Executive Order (E.O. 13295 as amended), and (2) communicable diseases that could pose a public health emergency of international concern, in accordance with the revised International Health Regulations of 2005, provided the disease meets specified criteria.

As a result of this final rule, HHS/CDC has also revised the Technical Instructions provided to panel physicians and civil surgeons to reflect the removal of the HIV testing requirement. The revised Technical Instructions will be immediately available to the public on the HHS/CDC Division of Global Migration and Quarantine Web site, located at the following Internet address: <http://www.cdc.gov/ncidod/dq/technica.htm>.

HHS/CDC will continue to work with DoS and DHS to ensure that panel physicians and civil surgeons are aware of the revision to the Technical Instructions. DHS and DoS will

determine the process for those applicants with HIV infection who have current applications pending.

V. Overview of Public Comments

The public comment period for the NPRM lasted for forty-five (45) days and ended on August 17, 2009. HHS/CDC received approximately 20,100 comments; of these, approximately 18,500 were largely similar “form” letters in favor of the proposed rule and also several “form” letters against the proposed rule. Comments were submitted by individuals; advocacy organizations; international and national public health agencies; immigration organizations; State and local health departments; medical associations; international, national and local AIDS organizations; corporate entities; various human rights; and other organizations from across the globe. Some comments were the collaborative effort of multiple groups. The comments will be permanently located in the docket for this final rule and maintained by HHS/CDC.

The sections below summarize and discuss the comments in detail: Comments on removing HIV infection from the definition of *communicable disease of public health significance*; comments on removing HIV testing from the scope of examinations; comments on the Economic Impact Analysis (EIA); and comments on technical correction. Data on the numbers of comments received in support of and opposed to the rule are provided below for informational purposes. However, these data are not the determinative factor in guiding public policy or in making these policy changes.

A. Comments on Removing HIV Infection From the Definition of Communicable Disease of Public Health Significance

Most commenters supported CDC’s public health assessment that HIV infection should be removed from the definition of *communicable disease of public health significance* as defined in 42 CFR 34.2(b) (approximately 19,500 comments were received in support of CDC’s preliminary determination).

Many commenters stated that the practice of excluding HIV-infected visitors and immigrants from the United States has no medical or public health rationale. Most of these individuals and organizations supported the language of the NPRM stating that the scientific evidence shows that HIV infection is not a risk to the general population through casual contact. Other comments submitted by individuals supporting equal rights and HIV advocacy groups

urged HHS/CDC to adopt the NPRM verbatim as a final rule that removes HIV infection from the definition of *communicable disease of public health significance* as defined in 42 CFR 34.2(b). In response, HHS/CDC has adopted the revisions to 42 CFR 34.2(b), as proposed. HHS/CDC has taken this action because based on scientific evidence, HIV infection is not a threat to the general population through casual contact and is no longer considered a significant public health risk given advances in public health practices and interventions for prevention and control.

A number of commenters supported the proposed rule for humanitarian reasons, stating that the former regulation (a) stigmatizes and discriminates against HIV-infected people, which include battered women and children; the lesbian, gay, bisexual and transgender (LGBT) community; or other vulnerable or already stigmatized populations; (b) separates loved ones; (c) denies U.S. businesses and research institutions access to talented workers; (d) bars students and tourists from accessing opportunities and supporting our economy; and/or (e) violates human rights by denying or interfering with the rights to life, freedom of movement, privacy, liberty and work. While HHS/CDC acknowledges these assertions, its mission is to protect public health and base decisions upon solid scientific and medical grounds. Therefore, there is no public health benefit for retaining this government-imposed barrier.

Several organizations and individuals noted that preventing HIV-infected travelers and/or immigrants from entering the United States is also counter to the nation’s longstanding leadership in fighting the HIV/AIDS epidemic internationally. These commenters noted that no international conference on HIV/AIDS has been held in the United States since 1990 because of the former regulations. In response, HHS/CDC notes that with this final rule, the United States will no longer be included among the other countries that maintain entry restrictions for HIV-infected individuals.

Many commenters suggested that the former regulations undermine public health efforts, including the fight against HIV/AIDS, by keeping HIV-infected researchers, advocates and experts from entering the country and by preventing HIV-infected immigrants from taking their medications in an effort to conceal their status from U.S. immigration authorities. Some commenters indicated that effective treatment of HIV infection requires a continuous antiviral regimen, and that interrupting antiviral

medication can result in difficulty treating the virus as well as higher viral loads, which is also the most important factor in transmissibility. In response, HHS/CDC acknowledges these humanitarian and medical considerations. This final rule, based on solid scientific and public health practices, removes HIV as a condition barring entry into the United States.

A number of commenters did not support CDC’s assessment that HIV infection should be removed from the definition of *communicable disease of public health significance* as defined in 42 CFR 34.2(b) (almost 600 comments). Many commenters who opposed the removal of HIV infection from the definition of *communicable disease of public health significance* cite financial concerns. They suggested that neither State health departments, Federal government, nor individuals should have to bear a significant financial burden to pay costs associated with treating HIV conditions in immigrants. In addition, many submissions pointed to the state of the economy and the recent debate over the strength of the health care system as a reason not to admit HIV-infected persons. Some commenters indicated that proof of ability to pay for health care should be required for HIV-infected immigrants, noting that HIV is a chronic, life-long infection, which is costly to monitor and even more costly to effectively treat.

CDC acknowledges these concerns, including those related to the potential financial burden that may result from this regulatory change. However, these reasons are not part of the scientific criteria used in determining whether HIV infection should be included as a defined *communicable disease of public health significance* and as a basis for admission to the United States. An individual infected with HIV will not pose a significant risk to the general U.S. population since HIV infection already exists as an endemic disease. Data have shown that decrease in transmission rates of HIV is directly correlated with national prevention efforts. CDC has and will continue to work on a number of fronts to reduce the impact of HIV across the nation by enhancing access to available prevention programs. These program activities include expanding HIV testing to increase knowledge of HIV status, improving surveillance to identify the leading edge of the epidemic, and exploring innovative and promising new prevention approaches. Communities and public health partners are working to tailor prevention efforts to meet local needs, mobilize

communities, and expand the reach of HIV prevention.

Some commenters noted that changing the regulation at this current time is ill advised, and several of the commenters opposed to the proposed rule requested that the waiver remain a requirement for entry into the United States. HHS/CDC acknowledges these comments, but notes that the Part 34 regulations do not address the criteria for a waiver of inadmissibility under Section 212 of the INA.

A few commenters asked why the U.S. government would put even one person at risk of contracting HIV from an immigrant. In response, as stated previously, scientific evidence confirms that HIV infection is not transmitted in casual settings. An arriving alien with HIV infection—or one adjusting status to that of a legal permanent resident—does not pose a public health risk to the general population through casual contact.

A few of these commenters, who did not support the removal of HIV infection as a condition of inadmissibility, expressed concerns that HIV infection should remain a *communicable disease of public health significance* or be accepted as a disease of “public health significance,” and cited morbidity and mortality rates of HIV infection domestically and internationally. HHS/CDC acknowledges that HIV infection is a serious illness and a major public health concern both domestically and internationally. However, HHS/CDC notes that the purpose of the NPRM was to determine whether HIV infection should remain as a disease that bans entry to the United States for *immigration purposes*. HHS/CDC, through this final rule, notes that HIV infection will no longer be included in the definition of *communicable disease of public health significance*, because scientific evidence suggests that it is not transmitted through casual contact.

Other reasons cited by commenters opposing the rule change include various comments such as: (a) HIV-infected persons should be allowed in for tourism but not for permanent relocation; (b) allowing HIV-infected immigrants into the country would allow new strains of HIV to circulate in the United States; (c) reporting requirements for HIV infection seem to indicate that HIV is a disease of public health significance; and (d) removing HIV infection from the disease list is inconsistent with leaving other sexually transmitted infections on the disease list. In response, HHS/CDC acknowledges these comments, however as previously stated, the basis for this

regulatory change is based on solid scientific knowledge and current public health practices. Additionally, HHS/CDC is reviewing the other sexually transmitted diseases on the disease list to determine whether additional revisions to Part 34 are warranted.

In summary, HHS/CDC appreciates all the comments received on the proposed change. After considering these comments, CDC has determined that HIV infection is not a communicable disease that is a significant risk for introduction and spread through casual contact to the general U.S. population, where HIV infection already exists as an endemic disease. Thus, HHS/CDC finalized the proposal to remove HIV infection from the definition of *communicable disease of public health significance*.

B. Comments on Removing HIV Testing From the Scope of Examinations

On the topic of removing HIV infection from the scope of examinations, some commenters stated that mandatory testing for HIV infection should no longer be required if they meet all other conditions of admissibility. These commenters also noted that maintaining testing while removing HIV infection from the definition of *communicable disease of public health significance* is legally and procedurally problematic. HHS/CDC maintains that it is appropriate to remove HIV testing from the immigration process, since HIV infection has been removed as a *communicable disease of public health significance*. As previously stated, HHS/CDC also notes that the regulations found at 42 CFR part 34 regulations do not specify testing for any illness that is not included in the definition of *communicable disease of public health significance*.

Other commenters stated that immigrants and refugees are not tested for other expensive chronic diseases (*i.e.*, diabetes, heart disease, obesity) and so, maintaining testing for HIV is discriminatory and would fuel the stigmatization of HIV-infected individuals. In response, HHS/CDC notes that testing for those chronic diseases are not within the scope of Part 34 regulations since they neither fall under the diseases listed in the INA for the purpose of a medical examination for U.S. immigration nor are they defined as a *communicable disease of public health significance*. HHS/CDC notes that this regulatory change will result in reducing stigma of HIV-infected persons.

Another group of commenters maintained that any mention of

serologic testing for HIV should be removed from the regulation. These comments stated that (1) the entry ban for HIV infection amounted to mandatory testing of all immigrants for HIV, which should not be included in routine medical screening of aliens seeking admission into the United States; (2) that people living with HIV should be allowed to enter the United States or adjust to permanent resident status if they meet all other conditions of admissibility; and (3) that when tested, many immigrants do not receive adequate counseling and in some cases have their privacy violated. For these reasons, these groups felt that testing for HIV should be separate from the immigration process.

In response, HHS/CDC acknowledges these humanitarian concerns but notes that HIV testing was required as a part of the 42 CFR part 34 rule when HIV infection was an inadmissible condition based on the definition of *communicable disease of public health significance*. With this final rule, HIV infection will no longer be contained in this definition and HIV testing will not be required as part of the medical examination.

Some comments in support of the proposed change to remove HIV infection from the Part 34 regulations also stressed the importance of HIV testing for immigrants and refugees for their own benefit and that of their potential sexual partners (approximately 30 comments). Specifically, several commenters said that testing for HIV enables immigrants to receive counseling and education related to HIV/AIDS, including information on treatment mechanisms and support systems, as well as prevention. These individuals and groups submit that health care outcomes are improved when testing is administered and access to treatment is determined or planned prior to arrival. Improved outcomes mentioned due to HIV testing prior to arrival included longer duration until AIDS diagnosis, reduced onward HIV transmission, reduced risk of active tuberculosis infection, and increased quality of life. In response, HHS/CDC acknowledges that diagnosis and linkage to high quality medical care in the context of the required immigration medical examination could positively impact the health of persons with HIV infection. HHS/CDC currently recommends and funds routine HIV screening in medical settings for all U.S. residents, including immigrants in contact with the health system.

Some individuals noted that in September 2006, HHS/CDC recommended that all persons age

13–64 undergo testing at least once for HIV. They suggested that keeping the HIV testing requirement for would-be immigrants would be consistent with HHS/CDC existing policy, would help to meet the HHS/CDC recommendation of voluntary testing, and would ensure that would-be permanent residents were aware of their HIV status.

HHS/CDC appreciates these comments and emphasizes the importance of adolescents and adults knowing their individual HIV status. However, removing the requirement for HIV testing at the time of the medical examination for immigration purposes will not prevent individuals from knowing their status upon and after arrival in the U.S. CDC has and will continue to work on a number of fronts to reduce the impact of HIV across the nation by enhancing access to available prevention programs. These program activities include expanding HIV testing to increase knowledge of HIV status, improving surveillance to identify the leading edge of the epidemic, and exploring innovative and promising new prevention approaches. Communities and public health partners are working to tailor prevention efforts to meet local needs, mobilize communities, and expand the reach of HIV prevention. Further, Part 34 regulations do not specify testing for any disease that is not included in the definition of *communicable disease of public health significance*. For example, other recommended screening procedures such as cholesterol tests, Pap smears, mammograms, or other diagnostic tests for the presence of asymptomatic chronic health conditions such as hepatitis B, are not conducted as part of the required medical examination. CDC recognizes that the medical exam provides a unique opportunity to both inform immigrants of their health status and, if warranted, link them with care. If, as a part of the medical examination for immigration, the panel physician detects a condition that might warrant additional follow-up or testing, CDC will continue to encourage the panel physician to inform the applicant about the condition and to seek appropriate medical care and counseling services. This would include anyone with symptoms suggestive of hepatitis, AIDS, or other chronic infectious diseases that are not inadmissible conditions.

Commenters also asked HHS/CDC to clarify how local public health departments and voluntary agencies will be funded and equipped to provide testing and counseling services to immigrants potentially infected with HIV if HIV testing is no longer included

in the required medical examination for U.S. immigration. In response, HHS/CDC will continue to work closely with its state and local partners in protecting the public's health. HHS/CDC currently provides funding to State and local health departments and community-based organizations for outreach and HIV counseling and testing programs. Immigrants would be eligible for services under these programs.

Some commenters suggested alternatives such as listing HIV infection as a Class B health condition or another designation to justify testing for immigrant applicants. In response, HHS/CDC reiterates that Part 34 regulations do not specify testing unless the illness is defined as a *communicable disease of public health significance*.

In summary, CDC appreciates all the comments received on the proposed change. After considering these comments, CDC has determined that HIV testing will no longer be included in the scope of examinations since HIV has been removed from the definition of *communicable disease of public health significance*. Therefore, as stated above, it is no longer necessary or appropriate to maintain HIV in the scope of examinations.

C. Comments on the Economic Impact Analysis (EIA)

1. General Comments on the Cost Analysis

HHS/CDC received a number of comments from individuals and organizations on the NPRM regarding the cost estimates of admitting HIV-infected visitors and immigrants into the United States (approximately 100). Many of the commenters complimented the quality of the economic impact analysis and the level of transparency provided regarding the methods and assumptions.

A majority of the individuals and organizations that provided comments on the economic impact analysis supported the removal of HIV infection from the list of communicable diseases as defined in 42 CFR 34.2(b), but suggested that the estimates provided in the NPRM overestimate the cost of the proposed rule to the United States taxpayer. Specifically, these individuals and organizations expressed concerns that the NPRM estimates did not differentiate costs between public and private payers; they noted that some HIV-infected immigrants would secure private insurance, some would pay out-of-pocket, and some would go without care or treatment. These commenters also noted that there is no data available to support the assumptions that HIV-

infected immigrants will seek public benefits. They stated that all immigrants entering the United States must document that they will not be a public charge and immigrants do not have access to entitlement benefits for five years.

Many of these commenters also noted that economic benefits of removing the HIV ban were not included in the cost analysis. Specifically, they noted that health care expenditures are a large portion of the United States economy. Health care expenditures for treatment of HIV infection contribute to the United States economy and the creation of jobs. Similarly, some of these individuals and organizations suggested that many HIV-infected immigrants will provide revenue for the United States through taxes, visa fees, and contributions to Social Security and that government-incurred expenses currently used to enforce bans would be reduced. Some commenters also noted that many immigrants would bring unique sets of skills and abilities, that can contribute greatly to the United States workforce and noted that these benefits were not captured in the analysis.

For these reasons, these individuals and organizations suggested that the cost estimates presented in the NPRM inflated the public costs of allowing HIV-infected immigrants into the United States. In other words, these commenters suggested that the cost estimates in the NPRM overestimate public sector expenditures resulting from this proposed rule. HHS/CDC acknowledges these comments on the health care expenditure estimates and recognizes that the estimates in the analysis do not consider all factors and that there are some limitations to the analysis.

Many of these individuals and organizations suggested that the cost estimates were high, but they also noted that the assumptions upon which the cost estimates were based were reasonable for this economic analysis.

In response to these comments, HHS/CDC notes that the analysis was not restricted to impacts to the U.S. Government. The HHS/CDC analysis is an analysis of the health care sector expenditures taken from a societal perspective. That is, all health care costs are included, regardless of who pays. However, HHS/CDC also acknowledges that the analysis is focused on the impact to the health care sector.

HHS/CDC acknowledges that the health care expenditures estimated in the economic analysis may be small relative to the total health care sector in the U.S. Nonetheless, Office of Management and Budget (OMB)

Circular A-4 on "Regulatory Analysis" (available at: <http://www.whitehouse.gov/OMB/circulars/a004/a-4.pdf>) directs agencies to assess all relevant impacts whether they be benefits, costs or distributional (regardless of payer).

HHS/CDC also acknowledges that allowing immigrants to enter and settle in the United States benefits the economy resulting from a number of additional economic activities. However, we are unable to quantify those potential benefits directly related to this rule.

Many organizations and individuals also noted that immigrants infected with HIV may consume fewer health care resources than immigrants with other chronic medical conditions. As such, these commenters suggested that including the cost model in the NPRM reflected inconsistencies in United States immigration policy. Specifically, they noted that the costs of treating HIV are raised as a concern in the proposed rule, but the costs of treating immigrants with other chronic conditions are not considered when determining immigrant status. In summary, they note that if the costs of treating immigrants with other significant health concerns are not considered in determining immigration policy, then HIV status should not be a factor in setting immigration policy.

HHS/CDC appreciates these comments and acknowledges the points made by these individuals and organizations. However, HHS/CDC conducted this cost analysis in adherence to the Office of Management and Budget (OMB) Circular A-4 requirements (available at: <http://www.whitehouse.gov/OMB/circulars/a004/a-4.pdf>).

Many of the individuals and organizations in opposition to the proposed rule often cited concerns that the potential costs of the proposed rule would result in an unacceptable, increased burden to the United States tax payers and to the United States health care system.

HHS/CDC notes that the purpose of the rulemaking was to determine whether HIV infection should remain as a *communicable disease of public health significance*. Through this Final Rule, HHS/CDC notes that HIV infection will no longer be a *communicable disease of public health significance*, because scientific evidence suggests that it is not transmitted through casual contact. Furthermore, we found no evidence to support the assertion that the rule would impose an unacceptable, increased burden on tax payers or the U.S. health care system.

One commenter noted that a significant number of visa applicants are the immediate relatives of U.S. citizens, for whom there is no numerical restriction. HHS/CDC acknowledges this point, but also notes that most immediate relatives of U.S. citizens are eligible for waivers under existing regulations. Much will depend on the assumed age structure of family-related immigration (*i.e.*, immigrants who are granted landed immigrant status on the basis of uniting families) and how many would have received a waiver absent this regulatory change. However, HHS/CDC has no reliable data measuring existing demand (*i.e.*, from family members who are HIV-infected and who will wish to immigrate here due to the change in regulations).

Two reviewers noted CDC may have overstated the costs of the proposed rule through calculation or transcription errors in the NPRM. HHS/CDC thanks these reviewers for their careful review of the analysis. HHS/CDC acknowledges that there was a transcription error and made the necessary edits in the analysis for the final rule.

2. Comments on a Technical Review of the EIA

In addition to the general comments on the Economic Impact Analysis (EIA), HHS/CDC also received a detailed technical review of the EIA from commenters. The comments received on this review concluded that the HHS/CDC cost assumptions were reasonable, but possibly overstated. These reviewers also indicated that a 5-year time horizon for analysis was reasonable.

This technical review noted that many of the economic benefits of removing the HIV ban were not included in the cost analysis. These reviewers further noted that the costs identified by HHS/CDC are health care expenditures that may benefit rather than harm the economy and suggest using a multiplier to estimate these economic benefits. One reviewer also suggested that HHS/CDC wrongly assumes that there will be no added economic benefit from new HIV-infected immigrants. The reviewer also contended that these immigrants would contribute to the economy and so the added health care expenditures CDC outlined would in some part be offset.

Several reviewers also noted that the costs estimated by the HHS/CDC model were small in proportion to the overall health care sector.

HHS/CDC acknowledges that data on the average annual health care costs of HIV treatment for immigrants are limited and may be lower than the estimates used in our analysis. We have

added language which indicates that the average annual medical costs for HIV treatment in the Ryan White and Medicaid Programs range from \$15,738 to \$17,790 per person. HHS/CDC also acknowledges that we did not include a quantitative estimate of the economic benefits of removing HIV as an inadmissible condition. We further acknowledge that the health care expenditures have a direct impact on the health of individuals. However, because no data exist to quantify these potential indirect effects on the economy, we have not estimated these effects, either through direct measurement or with the use of a multiplier.

HHS/CDC acknowledges that the health care expenditures estimated in the economic analysis may be small relative to the total health care sector in the U.S. Nonetheless, OMB's Circular A-4 directs agencies to assess all relevant impacts whether they be benefits, costs, or distributional (regardless of payer).

One of the reviewers suggested that it would be helpful if HHS/CDC explicitly stated that the costs to be borne by the federal government are a fraction of the figure described as "costs" in the NPRM. The reviewer also felt that it would be helpful if HHS/CDC would highlight that the CBO analysis states that the government has already identified a mechanism for offsetting the costs through visa fees.

The reviewer also suggested that the assumption that the prevalence of HIV infection among those immigrating to the U.S. will be the same as the prevalence in the general population of a particular region is questionable. However, although the reviewer notes the lack of reliable data may make this assumption reasonable, the reviewer believes that the assumption is a likely overestimation.

This reviewer also suggested that the assumption that there are a fixed number of immigrants is a flawed assumption because 40-47% of all immigrants are not subject to numerical caps. Therefore, immediate relatives would not replace an immigrant who is HIV negative. The reviewer finally states that the assessment of the economic impact of lifting the ban should also take into account the economic benefits.

HHS/CDC thanks the reviewer for the thoughtful and thorough examination of the proposed rule and the economic model. The reviewer is correct in the statement that all of the costs are not those to the government. Consistent with OMB's Circular A-4, the HHS/CDC analysis is an analysis of the health care sector costs taken from a societal

perspective; that is, all health care costs are included, regardless of payer.

HHS/CDC acknowledges the uncertainty in the estimate of HIV prevalence among immigrants who change their status to legal permanent residents, and the argument can be made that the estimate of prevalence should be higher or lower. Thus HHS/CDC chose to use a range. Further, HHS/CDC acknowledges that the range is "wide." However, HHS/CDC believes that the range provides an important understanding of the limitations of the available data.

The reviewer further commented that the model fails to account for the economic benefits that those immediate family member immigrants would bring to the U.S. economy. HHS/CDC notes that the purpose of the HHS/CDC model was to account for the direct impact to the changes in policy to the health care sector and not to account for ancillary economic benefits. HHS/CDC also notes that although it thoroughly and carefully examined the direct effects of the proposed rule change, there are limitations to the analysis. Finally, HHS/CDC points out that there is a limit on the number of immigrants allowed into the U.S. each year. Family-related immigration is usually outside those limits. Again, HHS/CDC acknowledges that it has no reliable data measuring the existing demand among families to reunite with their loved ones. In addition, HHS/CDC notes that this point is probably only valid for an initial period following the change in regulations, where there would be a catch-up phase.

D. Comments on Technical Correction

Two comments were received that provided the following technical correction: "In section II, Background, part I (p. 31798), last sentence, the proposed rule should state that the grounds of inadmissibility for specific health related grounds also pertain to most aliens in the United States who are applying for adjustment of their status to that of lawful permanent resident. There are few exceptions, e.g., applicants under INA 249, 8 U.S.C. 1259 (registry) or under INA 245, 8 U.S.C. 1255 (m) (U nonimmigrant status/U visa holders) are exempt from the health-related grounds of inadmissibility at INA 212(a)(1)(A), (8 U.S.C. 1182 (a)(1)(A))". CDC has accepted this technical change and amended the preamble text to reflect this.

VI. Conclusions and the Final Rule

Therefore, HHS/CDC amends 42 CFR 34 as follows: HIV infection is removed from the definition of a *communicable*

disease of public health significance as defined in 42 CFR 34.2(b), and references to HIV are removed from the scope of examinations in 42 CFR 34.3. As a result, beginning on the effective date of this rule, HIV infection will no longer be an inadmissible condition, and HIV testing will no longer be required for those aliens who are required to undergo a medical examination for U.S. immigration purposes.

HHS/CDC has considered the rationale for all the public comments on the proposed rule. The vast majority of comments support the NPRM as written, with less than 3% of all commenters opposed to the changes in the NPRM.

HHS/CDC believes that the positive benefits of this regulatory change outweigh the costs. After considering public comments, as well as the most recent scientific and public health data available, HHS/CDC has decided to promulgate the final regulation as proposed in the NPRM.

HHS/CDC will revise the Technical Instructions provided to panel physicians and civil surgeons, as needed, regarding the removal of required HIV testing, and this information will also be immediately available to the public on the HHS/CDC Division of Global Migration and Quarantine Web site, located at the following Internet address: <http://www.cdc.gov/ncidod/dq/technica.htm>. HHS/CDC will also work with DoS and DHS to ensure that panel physicians and civil surgeons respectively are aware of the revision to the Technical Instructions regarding the removal of required HIV testing.

VII. 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 final rule is an economically significant action under the Executive Order.

In the analysis that follows, we assess the potential impacts of removing HIV infection 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.

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 infection as a "communicable disease of public health significance." Now that the statute provides discretion, HHS/CDC is taking this action to reflect current scientific knowledge and public health best practices, and to reduce stigmatization of people who are HIV-infected. This final rule is not intended to correct any market failure, but to remove a government-imposed barrier that does not provide a significant public health benefit.

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 inadmissible 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 risk 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 inadmissible 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 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 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 *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 infection 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 examinations 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. These results may be counter to HHS/CDC objectives of reflecting current scientific knowledge and public health best practices, and reducing stigmatization of people who are HIV-infected. Therefore, as discussed below in the third approach, HIV testing, consistent with CDC's

recommendations for general screening, would be available.

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 infection during the immigration medical examination. 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 groups other than lawful permanent residents (e.g. refugees) 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 42 CFR part 34: Medical Examination of Aliens affects 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. With this final rule, the waiver process will no longer be necessary. Data on the number of waivers granted annually based on HIV status are not available. For example, in Fiscal Year 2007, the Department of State reported that its consular officers found 746 applicants for immigration ineligible for admission to the U.S. under the communicable disease grounds of INA 212(a)(1)(A)(i). The number of applicants 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 applicants such as visitors and refugees 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 (range of 1.02 to 6.09) immigrants per 1,000

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 typical 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 (range of 1.02 to 6.09) HIV-infected immigrants per 1000 immigrants yields an estimated 4,275 (range of 1,073 to 6,409) 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 how 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 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 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]).

E. Analysis of Impacts

In this final rule, HHS/CDC is removing 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 inadmissible 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. To the extent the final 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.

1. Potential Benefits

The benefits from this action are difficult to quantify. Based on the estimate above, this rule would allow perhaps roughly 4,275 (range of 1,073 to

6,409) 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 final rule removing HIV infection from the definition of *communicable disease of public health significance* and from the scope of examinations will remove stigmatization of 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.

Though this rule is assumed to not have an impact on the total number of immigrants annually admitted as legal permanent residents, we note that immigration, in general, produces net economic gains for the United States.[11].

2. Impact on Health Care Expenditures

As previously noted, 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 notes that this analysis is an analysis of the health care sector costs taken from a societal perspective; that is, all health care costs are included, regardless of payer. The costs to be borne by the Federal government are only a part of the total costs described below.

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 health care 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 off-set 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 examination [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 underestimated since as treatment options increase, the benefits such as quality of life and lifespan will increase as will costs. However, these expenditures may be overestimated since it is not clear to what extent immigrants will seek and receive even the 2004 standard of care. Expenditures may also be overestimated if only including direct medical costs, as is done for the Ryan White Block Grant and Medicaid Programs, where average annual costs range from \$15,738 to \$17,790 per person.

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-infected 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 regulation, as the cumulative number of HIV-infected immigrants almost doubles, so will these annual 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).

3. 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. The analysis for this final rule 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-health care costs.

4. 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. 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 section 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 the 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 is relatively small 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.

5. Onward Transmission

Though difficult to quantify with precision, there will likely be some additional cases of HIV infection 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) \times 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 show 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.

F. Summary of Impacts

We have made our best attempt to capture the likely effects of the rule, but there are significant uncertainties in this estimation effort. For example, 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 and other 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)
BENEFITS			
Total number of HIV-Positive Immigrants present in the U.S. at year five who would not otherwise be able to immigrate.	15,755	3,956	23,622
Qualitative	1. Will reduce stigmatization of HIV-infected people. 2. Will bring family members together who had been barred from entry, thus strengthening families. 3. Will permit 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. 4. 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.		
COSTS			
Total number of HIV-Positive cases due to 1.51% onward transmission connected with U.S. Immigrants.	676	170	1,014
Annualized Monetized Health care Expenditures from onward transmission.	\$14 million	\$4 million	\$22 million.
Qualitative	1. Shortened lifespan and reduction in quality of life even with treatment. 2. Decreased productivity.		
TRANSFERS			
Annualized Monetized Health care Expenditures.	\$342 million	\$86 million	\$513 million.
Share for Federal Payers	Depends upon assumptions of who pays annualized monetized medical costs; likely to be small given restrictions on Federal assistance to new immigrants.		

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

The primary benefit of this rule is that each year an additional 4,275 (range of 1,073 to 6,409) immigrants who otherwise qualify for entry but are

denied based solely on HIV status will now be able to enter the country. Although we are unable to quantify all of the benefits of this change in policy,

we believe it will help reduce stigmatization of HIV-infected people; bring family members together who had been barred from entry (thus

strengthening families); and allow HIV-infected immigrants with skills in high demand to enter the U.S. to seek employment and contribute as productive members of U.S. society, and if they are able to obtain better health care in the United States, to improve health outcomes and productivity. There are also ethical, humanitarian, distributional, and international benefits that are important but difficult to quantify. [We note the words of Executive Order 12866: "Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider."'] We observe as well that in the context of the U.S. HIV/AIDS prevalence, currently estimated at roughly 1 million persons [1] the 3,956 to 23,622 HIV-infected immigrants in five years represents 0.4% to 2.4% of the national total of persons living with HIV/AIDS.

The main cost of this rule is the potential for onward transmission to U.S. residents who are not infected with HIV. As we noted in the previous discussion, however, our 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 assumption will in some cases be unrealistic, because U.S. persons who are infected by HIV-infected immigrants may engage in behaviors that expose them to HIV infections, regardless of the source of infection. It is possible, of course, that at least some of the additional infections are occurring earlier than they otherwise would have. To the extent that this is so, the 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 show that onward transmission has declined over time [19]. Even given these caveats, in the context of the new U.S. incidence of HIV, currently estimated at roughly 56,000 [32], the number of new onward transmission cases due to the rule change, 65 (ranging from 0 to 261) in year one represent 0.1% (ranging from 0 to 0.5%) of the total new annual cases of HIV in the U.S. (as described in Section 5. Onward Transmission). The monetized costs including the treatment cost of the onward transmission cases, are relatively modest. We add, however,

that these monetized costs are incomplete, because they do not include the health costs in terms of reduction in quality of life and longevity even with treatment.

On the other hand, health care expenditures for immigrants, although a quantifiable and relevant impact of the rule, are not really "costs" of the rulemaking. Unlike in the case of onward transmission, these immigrants already have the disease and will now be purchasing healthcare in the U.S. that they would have purchased in their home country (similar to spending on other services such as housing or education). However, since the spending pattern may be systematically different for HIV immigrants, we quantify and report these effects as a "transfer" from the perspective of this rulemaking—payments from immigrants and/or their 3rd party payers to U.S. providers of care. We estimate the annual transfer payments to be \$86 million to \$513 million. The share of these payments by Federal payers is likely to be small given the restrictions on Federal benefits to new immigrants.

Given these potential impacts, we conclude that the benefits of the rule justify its costs, and 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.

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VIII. Final Regulatory Flexibility Analysis

HHS/CDC has considered the final 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 they were not compatible with current U.S. regulations. This analysis appears in the 'alternatives' section.

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

IX. 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 does not create an environmental health or safety risk.

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. HHS/CDC will discontinue the use of this form, for a reduction of 67 burden hours for this approved data collection.

D. Environmental Assessment

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 rule does not require a Federal taking of private property, the provisions in the Executive Order are not applicable.

G. Executive Order 13132: Federalism

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

HHS/CDC has determined that this rule 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 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 this 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 this 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 regulatory action to determine whether such an action would affect family well-being. HHS/CDC has assessed the impact of this regulation and has determined 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 this 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 did not receive any comments seeking clarity on language used in the NPRM. HHS/CDC has attempted to use plain language in promulgating this Final Rule.

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 amending 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 paragraphs (6) through (9) respectively.

■ 3. Amend § 34.3 by revising paragraphs (b)(1)(i), (e)(1) introductory text, (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) * * *

(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 *M. tuberculosis* antigens, or chest x-ray examination for good cause, upon application approved by the Director.

* * * * *

(5) *How and where performed.* All chest x-ray 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: October 22, 2009.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.
[FR Doc. E9-26337 Filed 10-30-09; 8:45 am]
BILLING CODE 4163-18-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 0907281181-91369-02]

RIN 0648-AX93

Fisheries of the Northeastern United States; Modification to the Gulf of Maine/Georges Bank Herring Midwater Trawl Gear Letter of Authorization

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.