

Dated: November 6, 2009.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Vaccination Requirements for U.S. Immigration Purposes

AGENCY: Centers for Disease Control and Prevention (CDC).

ACTION: Final notice of agency action.

DATES: This agency action is effective December 14, 2009.

FOR FURTHER INFORMATION CONTACT:

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SUMMARY: On April 8, 2009, the Centers for Disease Control and Prevention (CDC) published a notice in the **Federal Register** (74 FR 15986) seeking public comment on proposed criteria that CDC intends to use to determine which vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) for the general U.S. population should be required for immigrants seeking admission into the United States or seeking adjustment of status to that of an alien lawfully admitted for permanent residence. This final notice describes the criteria that CDC has adopted.

At present, CDC requires all vaccinations against vaccine-preventable diseases explicitly listed in section 212(a)(1)(A)(ii) of the Immigration and Nationality Act, as well as all vaccinations recommended by the ACIP for the general U.S. population. After the effective date of this notice, CDC will continue to require the vaccinations explicitly listed in section 212(a)(1)(A)(ii)—mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B, and hepatitis B—and, for all other vaccinations recommended by ACIP for the general U.S. public, CDC will begin requiring only those for which there is a public health need at the time of immigration/change of status based on the following criteria:

1. The vaccine must be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population, and

2. At least one of the following:

a. The vaccine must protect against a disease that has the potential to cause an outbreak.¹

b. The vaccine must protect against a disease that has been eliminated in the United States or is in the process for elimination in the United States.²

SUPPLEMENTARY INFORMATION:

Background

Under section 212(a)(1)(A)(ii) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(a)(1)(A)(ii)), any alien who seeks admission into the United States as an immigrant, or who seeks adjustment of status to the status of an alien lawfully admitted for permanent residence, is inadmissible into the United States if the alien is unable to present documentation of having received vaccination against “vaccine-preventable diseases, which shall include at least the following diseases: Mumps, measles, rubella, polio, tetanus and diphtheria toxoids, pertussis, *Haemophilus influenzae* type B, and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee on Immunization Practices.” Aliens subject to this provision may apply for a waiver in certain circumstances, e.g., if the vaccination is not medically appropriate or contrary to the alien’s religious beliefs or moral convictions.

Medical examinations, including an evaluation to determine whether an alien has received these vaccinations, are authorized under section 232 of the INA (8 U.S.C. 1222). Under sections 212(a)(1) and 232 of the INA (8 U.S.C. 1182(a)(1), 1222), and section 325 of the Public Health Service Act (42 U.S.C. 252), the Department of Health and Human Services (HHS) publishes regulations establishing requirements for the medical examination. The Secretary of HHS has delegated the authority for administering these regulations to the Centers for Disease Control and Prevention (CDC). The regulations are codified in 42 CFR part 34. Panel physicians and civil surgeons, through contractual agreements and by

¹ For purposes of this Notice, “outbreak” means the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time.

² “Elimination” is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required.

designations with the Department of State (DOS) and the Department of Homeland Security (DHS), respectively, conduct the medical examinations in accordance with these regulations. CDC also publishes Technical Instructions (TIs) for the medical examinations, which must be followed by panel physicians and civil surgeons. The vaccinations required by the INA are listed in the Technical Instructions (*see* <http://www.cdc.gov/ncidod/dq/technica.htm>).

Since 1996, when the vaccination requirement was added to the INA, CDC has required immigrants subject to the INA vaccination requirement to receive all vaccinations routinely recommended by the Advisory Committee on Immunization Practices (ACIP) for the general U.S. population. Vaccine development has evolved since 1996 and, in addition, a greater number of vaccines are recommended by ACIP than were recommended when the legislation was enacted. As a result, CDC is reassessing which of these vaccinations are appropriate for immigration purposes, taking into consideration both the context in which they are given as well as the interests of public health.

To meet the threshold for consideration, a vaccine must first be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population. After this determination is satisfied, the vaccine must protect against (1) a disease that has the potential to cause an outbreak, and/or (2) a disease that has been eliminated in the United States or is in the process for elimination in the United States. Outbreak is defined as the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time. The determination of an outbreak may be made in a variety of scenarios. For example, an outbreak may be determined by comparing the current number of cases of disease with the background rate of the disease. The “background rate” of disease is the rate at which the disease usually occurs, at a particular time, in a particular population, or in a particular place. Therefore, the occurrence of a disease above the background rate, so that more people than usual or an unexpected group of people have become ill with the same disease in a given geographic area, or over a given period of time, could be viewed as an outbreak.

In general, and as observed through previous experience, an outbreak is associated with a public health response (e.g., initiation of an investigation,

dissemination of prophylaxis, or public health messaging to change behavior).

CDC will also consider whether the disease has been eliminated in the United States or is in the process for elimination in the United States. "Elimination" is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate public health efforts; continued measures to prevent re-establishment of transmission are required.³ Therefore, if a vaccine is an age-appropriate vaccine as recommended by the ACIP for the general U.S. population, and the disease is in the process for elimination in the United States, it will be required for immigration purposes. The prevention of outbreaks and progress toward elimination represent two core public health goals. These criteria aim to prevent outbreaks and the re-introduction of vaccine-preventable diseases that have been eliminated or are in the process for elimination in the U.S. through the immunization of immigrants.

Congress mandated vaccinations for immigrants to decrease the public health threat from disease importation. Outbreak potential and absence of a vaccine-preventable disease in the United States (because of elimination or movement toward elimination through vaccination) are the critical public health concerns in determining which vaccines should be mandated for immigration to the United States. Evidence shows that disease importation contributes to many current vaccine-preventable disease outbreaks in the United States, and is solely responsible for outbreaks of eliminated diseases. For example, close to 90% of the measles cases reported in the U.S. during 2008 were either acquired abroad or linked to imported cases resulting in 7 outbreaks involving 135 persons.⁴ Some of these cases are attributable to traveling unvaccinated U.S. citizens. Such disease vulnerability among U.S. citizens is beyond the scope of this notice and should be addressed by states and other public health authorities. The INA immigrant vaccination mandate, however, provides a significant opportunity to reduce the potential of disease importation, in particular of those diseases (1) where a single case has the potential to spread

widely or (2) to threaten reintroduction of an eliminated disease.

Disease prevention vigilance at the borders through imposition of vaccination mandates focused on those diseases of outbreak or elimination significance serves a critical role in the multi-layered public health response to vaccine-preventable diseases. State vaccination mandates for school attendance and availability of vaccines for children through public health programs add other layers to that public health response. Working together, these layers result in vibrant vaccination coverage that protects the health of our citizens, individually and as a whole.

Further, it should be noted that given the existence of this multi-layered public health system for assuring adequate vaccination of all Americans, determination that a vaccine should not be mandated at time of immigration or change in status is not relevant to and should not in any way be considered a factor in determining whether or not that vaccine should be required for school entry or otherwise mandated by a state or other public health entity. Immunization mandates at various times and places are a highly important and effective public health tool for preventing vaccine-preventable diseases.

CDC has developed and accepted the criteria described in this Notice specifically for the required medical examination performed for U.S. immigration purposes. CDC stands behind all ACIP recommendations for the general U.S. population of which the immigrants will become part. CDC expects that such individuals will avail themselves of those vaccines not mandated for immigration as they make future wise medical decisions for themselves and encounter the other public health layers present to minimize vaccine-preventable diseases in our communities.

Implementation of Specific Vaccination Criteria

ACIP recommendations serve multifactorial purposes, including optimizing individual health status, protecting the public health of the Nation, and providing technical guidance for State-based mandates for school, child care, employment, and other settings. However, to date, the ACIP recommendations for the general U.S. population have been applied to aliens seeking admission into the United States without further consideration of the public health impact and need of these immunizations at the time of the medical examination for immigration.

CDC believes specific public health criteria that focus on preventing infectious diseases that can cause outbreaks or are in the process of elimination should be used to determine which ACIP-recommended vaccinations for the U.S. population are appropriate to mandate for aliens seeking admission into the United States or seeking to adjust their status to that of lawful permanent resident at the time of the medical examination.

On April 8, 2009, CDC published a notice in the **Federal Register** seeking public comment on criteria CDC proposed to be used for these purposes. See 74 FR 15986. CDC proposed the following criteria:

1. The vaccine must be an age-appropriate vaccine, as recommended by ACIP for the general U.S. population, and
2. At least one of the following:
 - a. The vaccine must protect against a disease that has the potential to cause an outbreak.⁵
 - b. The vaccine must protect against a disease that has been eliminated in the United States, or is in the process for elimination in the United States.⁶

CDC received a total of forty (40) comments to the **Federal Register** notice, some of which contained multiple topics and some of which were the collaborative effort of multiple groups. Twenty-six comments were received regarding Human Papillomavirus (HPV) vaccine specifically, including two comments that suggested alternatives HHS/CDC could adopt if the HPV vaccine were not removed from the list as a result of the application of the adopted criteria. Twenty-four comments were received regarding HHS/CDC's current practice of requiring vaccines for the purpose of immigration. Nineteen comments were received that discussed the proposed criteria to be used in determining which vaccines recommended by ACIP for the U.S. population should be required for immigration purposes. Ten comments were received regarding the vaccine for the prevention of herpes zoster (zoster vaccine). Three comments were received regarding HHS/CDC's technical instructions. Finally, nine comments were received which were either outside the scope of the Notice or beyond the scope of HHS/CDC's mission. Below is

⁵ For purposes of this Notice, "outbreak" means the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time.

⁶ "Elimination" is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required.

³ CDC. Dowdle WR. The Principles of Disease Elimination and Eradication. MMWR Supplement 1999; 48(SU01):23-7.

⁴ CDC. Update: Measles—United States, January–July 2008. MMWR, 22 August (2008) 57(33):893–896.

a summary of public comments received and CDC's responses to those comments.

I. Comments Regarding the Current Process

One commenter noted that the current requirements work very well in practice and wondered what might be accomplished by a change.

Response: The current process for determining which vaccines should be required does not take into consideration the purpose of the medical examination for U.S. immigration, i.e., to prevent the importation of infectious diseases of public health significance. The change to the current process will allow for the necessary flexibility to identify vaccines from a growing list of vaccines against vaccine-preventable diseases with highest public health impact (as defined in the criteria) at the time of the medical examination.

Some commenters asserted that CDC's current practice of listing all ACIP vaccines in its technical instructions is too broad and inflexible, and likely to lead to unnecessary requirements that do not allow immigrant women to make an informed decision about whether to obtain certain recommended vaccines.

Response: The issue of consent is not a subject of this notice. Congress has mandated (with opportunity for medical/religious/moral waiver) that particular vaccines be received by immigrants and that other vaccines also be received by them based on ACIP recommendations. Therefore, beyond application of waivers, immigrants do not have discretion to choose which mandated vaccines to receive.

Some commenters wondered why certain vaccines are required for immigrants and not U.S. citizens. Other commenters incorrectly assumed that the **Federal Register** Notice and proposed criteria applied to refugees.

Response: Vaccination requirements for aliens seeking admission into the United States are based on the Immigration and Nationality Act (INA). Section 212(a)(1)(A)(ii) of the INA requires any person who seeks admission as an immigrant, or who seeks adjustment of status to that of an alien lawfully admitted for permanent residence to document proof of vaccination of having received vaccination against certain vaccine-preventable diseases as listed in the statute or recommended by ACIP. The vaccine requirements provided in the INA do not apply to U.S. citizens. Additionally, the current vaccination requirements apply to refugees only when they apply to adjust their status to

lawful permanent resident, typically one year after arrival into the United States.

Several commenters expressed concern that the DHS waiver for moral convictions or religious reasons is an ineffective tool because waiving all vaccinations for an individual—instead of waiving particular vaccinations—results in a completely unvaccinated individual and, therefore, a threat to public health. Further, not all immigrants are aware that such a waiver exists, or it may not be an option for them because they previously received vaccines.

Response: This issue is outside the scope of the request for comments—HHS does not issue waivers with respect to immigrant vaccination mandates. This is a function carried out by DHS under its regulations.

II. Comments Regarding the Proposed Criteria

Some commenters agreed with the criteria and urged CDC to adopt them as proposed.

Response: CDC has adopted the criteria as proposed. Application of criteria to ACIP recommendations will begin thirty (30) days after publication of this Notice.

Some commenters expressed concern over the potential for an overly broad reading of proposed criterion 2b, which states: "is in the process for elimination in the United States." These commenters suggested this text be narrowed to reflect an appropriate standard by which to evaluate the current and potential mandatory vaccinations for immigrants.

Response: CDC follows an accepted definition for elimination of infections that states: "Elimination is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required."⁷ Hence, in order to meet the criterion of an infection being in the process of elimination, deliberate efforts need to be in place for the elimination of infection, not merely the prevention of infection. CDC will rely on subject-matter experts, including national and international public health bodies such as the ACIP and the World Health Organization (WHO), to make such determinations. To date, only measles, polio, and rubella are considered to have been eliminated (or, in the case of

polio, "eradicated") in the United States.

One commenter raised concern that "potential to cause an outbreak," as defined in the April 8, 2009 **Federal Register** Notice, is vague and overly broad and could be used to make a specious case that it encompasses noninfectious diseases. HPV, which can lead to cancer, is currently the most common sexually transmitted disease in the United States, which could be interpreted as being "an outbreak." This commenter suggested that the definition of outbreak should be narrowed to include the spread of disease through the respiratory route or common public contact, and should also reference the difficulty of containing the spread due to unavoidable exposure.

Response: CDC is adopting the language provided for in the **Federal Register** notice because it is widely established and accepted in public health. CDC recognizes that the mode of transmission itself does not define an outbreak potential. Similarly, as discussed in the Background section above, high prevalence in and of itself does not constitute an outbreak—in that it does not automatically mean there are "more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time" per the applied definition of an outbreak. For endemic diseases, an outbreak occurs when the incidence rises above the normal expected level. While HPV is a common infection, the occurrence of more cases than expected (as defined by an outbreak, discussed above) is not met. Further, HPV has not been eliminated, nor is in the process of elimination, in the United States. Therefore, because HPV does not meet the adopted criteria, it will not be a required vaccine for immigrant and adjustment of status to permanent residence applicants.

Some commenters rejected the proposed criteria and developed a list of vaccinations which should be required based upon their personal beliefs or practices.

Response: Commenters should be aware that not all vaccination requirements are subject to change as a result of the adoption of these criteria. For example, vaccinations are not required for any alien for whom a civil surgeon, medical officer, or panel physician certifies that the vaccination would not be medically appropriate or for whom the vaccination requirement would be contrary to religious beliefs or moral convictions, in accordance with regulations promulgated by DHS. Further, commenters should be aware

⁷ CDC. Dowdle WR. The Principles of Disease Elimination and Eradication. MMWR Supplement 1999; 48(SU01):23–7.

that most adopted children 10 years of age or younger are not required to receive such vaccinations provided certain requirements are met. This includes a requirement that, prior to the admission of the child, an adoptive or prospective adoptive parent of the child who has sponsored the child for admission as an immediate relative must execute an affidavit stating that the parent is aware of the vaccination requirements and will ensure that the child receives the required vaccinations within 30 days of the child's admission, or earlier if medically appropriate.

III. Comments Regarding the HPV Vaccine

CDC received numerous comments both advocating for and against inclusion of HPV vaccine.

Response: CDC has applied the criteria and determined that once these criteria become effective December 14, 2009, the HPV vaccine will not be required for aliens seeking admission as an immigrant or seeking adjustment of status to that of an alien lawfully admitted for permanent residence. In reaching this decision, CDC applied the adopted criteria. Genital infection with HPV is an extremely common infection due to its efficient transmission via sexual intercourse. There are approximately 6 million incident infections occurring annually in the United States. Over half of sexually active men and women will develop HPV infection at some point in their lives and 15% of all Americans have current infection with HPV.⁸ Even more individuals will have been infected previously in their lives.

Although millions of HPV infections occur annually, most are asymptomatic and resolve. About 10,000 cases of cervical cancer (the most important biologic outcome of HPV infection) develop annually in the United States. Because HPV infection is common in the general US population, is asymptomatic, and because it is not possible to distinguish infections which resolve spontaneously from those that result in cervical cancer, HPV is not the target of outbreak control. Rather a routine vaccination program is recommended to prevent infection. Similarly, HPV is not the target of a disease elimination campaign in the United States.

Therefore, while HPV may be an age-appropriate vaccine for an immigrant applicant, HPV neither causes outbreaks nor is it associated with outbreaks (per

explanation in the background section). Further, HPV has not been eliminated, nor is in the process of elimination, in the United States. Therefore, because HPV does not meet the adopted criteria, it will not be a required vaccine for immigrant and adjustment of status to permanent residence applicants.

One commenter asked CDC to clarify if the phrase "through 26 years of age," as written in the Technical Instructions for administration of the HPV vaccine, means "past the age of 26 and up to 27," or "up to the age of 26."

Response: CDC clarifies that "through 26 years of age" means past the age of 26 and up to the 27th birthday.

IV. Comments Regarding Alternative Approaches

One commenter suggested that if, as a result of these published criteria, the HPV vaccine is not removed from the list of required vaccinations, aliens should be allowed to forego a required vaccination on the basis that it protects against a noninfectious disease. Further, that commenter asserted that there should be no charge or application for opting out of such vaccines, and the Attorney General should not have the discretion to deny aliens this option.

Response: As indicated above, when the newly adopted criteria become effective (30 days after publication of this Notice), the HPV vaccine will no longer be required for immigration purposes. For those vaccines mandated for immigration, the only basis for opting out is receipt of a medical, religious, or moral convictions waiver. Whether or not the Attorney General has the authority to require a fee or application as part of a waiver process for vaccinations, is beyond the scope of this Notice.

One commenter requested CDC to direct the ACIP to modify its recommendation to state that the HPV vaccination should not be mandated for immigrants.

Response: The nature of an advisory committee is to provide its independent, unfettered expertise and advice to the agency, as described in the committee's administrative charter. The agency does not mandate that it receive any particular advice.

One commenter urged CDC to direct the U.S. Citizenship and Immigration Services agency (USCIS) to suspend the HPV vaccination requirement for immigrants applying to adjust their immigration status or obtain visas for the United States.

Response: HHS/CDC has no authority to direct component agencies within DHS to take action. However, HHS/CDC has determined that the HPV vaccine

does not meet the necessary elements of the proposed criteria and will no longer be required for immigration purposes once the criteria become effective (30 days after publication of this notice).

V. Comments Regarding the Zoster Vaccine

Several commenters opposed the requirement of Zoster vaccine based upon the proposed criteria, and further found the costs to immigrants and refugees for this vaccine to be prohibitive.

Response: Upon application of the criteria adopted in this final notice, CDC has determined that Zoster vaccine will no longer be required for immigration purposes once the criteria become effective (30 days after publication of this notice). In reaching this decision, CDC applied the adopted criteria. Varicella Zoster Virus (VZV) is an exclusively human pathogen that infects approximately 98% of the adult population in the United States.⁹ Approximately 1 million new cases of Zoster occur in the United States annually and approximately one in three persons in the general population will develop zoster during their lifetime. These statistics alone indicate that VZV has neither been eliminated, nor is in the process of elimination in the United States.¹⁰ Further, Zoster neither causes outbreaks nor is it associated with outbreaks of varicella: Its high prevalence in the U.S. is in keeping with the background rate of the disease (i.e., no more people than usual, or an unexpected group of people, have become ill with VZV in a given geographic area in the U.S. over a given period of time). Therefore, because Zoster does not meet the criteria, it will not be a required vaccine for immigrant and adjustment of status to permanent residence applicants.

VI. Comments Regarding Technical Instructions

One commenter requested that state immunization programs be notified of any change in vaccination requirements.

Response: Any changes in the vaccination requirements for immigrant visa and adjustment of status applicants are posted on the CDC and DHS (USCIS) Web sites. Thus, they are available to the public and all organizations (e.g.,

⁹ Kilgore PE, Kruszon-Moran D, Seward JF, et al. Varicella in Americans from NHANES III: implications for control through routine immunization. *J Med Virol* 2003;70 Suppl 1:S111-8.

¹⁰ CDC. Prevention of herpes zoster: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2008;57(No. RR-5):1-30.

⁸ Dunne EF, Unger ER, Sternberg M, et al. Prevalence of HPV infection among females in the United States. *JAMA* 2007;297(8):813-819.

civil surgeons, health departments) involved in vaccination issues.

One commenter requested that the Technical Instructions be updated to reflect any change in vaccination requirements.

Response: The Technical Instructions are routinely revised to reflect needed changes (e.g., addition of new vaccines). Two key changes to the Technical Instructions are based on the adoption of the criteria in this **Federal Register** Notice, i.e., that neither the HPV nor Zoster vaccines be required as part of the medical examination. These changes, which become effective 30 days after publication of this notice, will be reflected in the revised Technical Instructions posted on the CDC Web site at <http://www.cdc.gov/ncidod/dq/technica.htm>.

One commenter suggested that the current Technical Instructions do not follow the ACIP recommendations and are confusing regarding the age-appropriate vaccinations and minimum intervals.

Response: The current Technical Instructions are based on age-appropriate vaccinations and minimum intervals of vaccine doses provided by the ACIP recommendations for the general population. The vaccine tables for children and adults based on the ACIP recommendations are located on CDC's Web site at the following Internet address: <http://www.cdc.gov/vaccines/recs/schedules/>.

One commenter requested that the Technical Instructions be reviewed (if not written) by the National Center for Immunization and Respiratory Diseases (NCIRD) staff who are very familiar with immunizations.

Response: The Technical Instructions are developed in coordination with numerous components of CDC, including NCIRD and other programs with expertise in immunization matters. Following their development, the Technical Instructions then undergo official agency clearance, which also includes review by relevant components of the agency. Ultimately, the Technical Instructions are published by CDC's Division of Global Migration and Quarantine (DGMQ), which is the component of CDC responsible for administering them for use by civil surgeons and panel physicians.

VII. Miscellaneous Comments

One commenter called attention to the incorrect deadline for submission of comments which was originally posted in the **Federal Register** Notice.

Response: CDC appreciates this comment and had already made changes to the original notice and published the

corrected date on April 20, 2009 in the **Federal Register** (74 FR 17966) to accurately reflect 30 days after the April 8, 2009, publication.

Another commenter urged the CDC to halt all immigration to the United States, thus making the vaccination issue moot.

Response: Immigration laws are promulgated by the U.S. Congress and implemented by DHS. While CDC administers regulations describing medical examinations that aliens must undergo, as described above, CDC has no authority over immigration matters.

Commenters requested that all people immigrating to the United States receive all available vaccinations to protect the U.S. public health.

Response: The current vaccination requirements are based on the Immigration and Nationality Act, which requires any person who seeks an immigrant visa or who applies for adjustment of status to lawful permanent resident to have certain specified vaccines, as well as those recommended by ACIP. CDC has adopted criteria for determining which of the vaccinations recommended by ACIP are appropriate for the immigration population, in order to take into consideration the highest public health impact as defined in the criteria at the time of the medical examination for U.S. immigration.

One commenter suggested that, rather than seek public comment on which vaccinations should be required for immigration purposes, CDC should focus on the connection between vaccines and autism.

Response: HHS has a statutory obligation to describe medical examinations certain aliens must undergo. This responsibility has been delegated to CDC/DGMQ. This notice is being implemented under that authority. While HHS/CDC does work on the subject of autism, it is outside the scope of this notice.

VIII. Final Action

After consideration of public comments received through this notice, as well as those received during an ACIP meeting held at CDC February 25–26, 2009, CDC is adopting the criteria as proposed and will begin applying the criteria to determine which vaccines recommended by ACIP for the general U.S. population will be required (in addition to those statutorily mandated) for immigrants in accordance with section 212(a)(1)(A)(ii) of the Immigration and Nationality Act, 8 U.S.C. 1182(a)(1)(A)(ii)). The current vaccine tables for children and adults based on the ACIP recommendations for

the U.S. population are located on CDC's Web site at: <http://www.cdc.gov/vaccines/recs/schedules/>.

The criteria that CDC is adopting today and will apply 30 days after publication of this notice are as follows:

1. The vaccine must be an age-appropriate vaccine as recommended by the ACIP for the general U.S. population, and

2. At least one of the following:

a. The vaccine must protect against a disease that has the potential to cause an outbreak.¹¹

b. The vaccine must protect against a disease that has been eliminated in the United States or is in the process for elimination in the United States.¹²

The updated vaccination requirements will be listed in the Technical Instructions (see <http://www.cdc.gov/ncidod/dq/technica.htm>) and will become effective 30 days after publication of this notice. CDC will continue to require the vaccinations explicitly referenced in section 212(a)(1)(A)(ii): Mumps, measles, rubella, polio, Tetanus and diphtheria toxoids, pertussis, Haemophilus influenzae type B and hepatitis B). All vaccines will remain subject to statutory waivers, if applicable. CDC will periodically review the list of vaccines recommended by ACIP for the general U.S. population to determine whether additional vaccinations fall within CDC's recommended criteria. Any changes to the list of required vaccines, which result from an application of these criteria, will be reflected in CDC's Technical Instructions, available to the public at <http://www.cdc.gov/ncidod/dq/technica.htm>). If there is a future need for CDC to reconsider these established criteria, CDC will solicit comments through publication in the **Federal Register**.

Dated: November 6, 2009.

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Chief Policy Officer, CDC, OSI.

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¹¹ For purposes of this Notice, an "outbreak" means the occurrence of more cases of disease than could be anticipated in a given area or among a specific group of people over a particular period of time.

¹² "Elimination" is the reduction to zero of the incidence of infection caused by a specific agent in a defined geographic area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required.