SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION

Vaccine Documentation Worksheet OMB Number 1405-0113 DS-3025

A. JUSTIFICATION

1. Why is this collection necessary and what are the legal statutes that allow this?

This collection is necessary to document information pertinent to an applicant's eligibility for a visa or refugee status under the Immigration and Nationality Act's (INA) medical grounds of inadmissibility at § 212(a)(1) by recording the results a medical examination required by § 221(d) (8 U.S.C. § 1201(d)). INA § 221(d) requires that prior to issuance of an immigrant visa to any noncitizen, the consular officer shall require such noncitizen to submit to a physical and mental examination in accordance with such regulations as may be prescribed. Under INA § 221(d), consular officers may require medical exams to determine whether a noncitizen is eligible for a nonimmigrant visa pursuant to the INA. The results of the medical examination are used to determine the noncitizen's eligibility for such a visa under the INA, including the health-related visa ineligibility grounds in INA § 212(a)(1). Additionally, INA § 412(b)(4)(B) (8 U.S.C. § 1522(b)(4)(B)) requires the United States government to "provide for the identification of refugees who have been determined to have medical conditions affecting the public health and requiring treatment."

Under INA § 212(a)(1)(A)(ii), a foreign national who seeks admission into the United States as an immigrant, or who seeks adjustment of status to the status of a noncitizen lawfully admitted for permanent residence, is inadmissible into the United States if the noncitizen 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, influenza type B and hepatitis B, and any other vaccinations against vaccine-preventable diseases recommended by the Advisory Committee for Immunization Practices ("ACIP"). As explained in the Center for Disease Control and Prevention's ("CDC") Criteria for Vaccination Requirements for U.S. Immigration Purposes, 74 Fed. Reg. 58634 (Nov. 13, 2009), the ACIP recommendation for use of a vaccination for the general U.S. population triggers a vaccine requirement under INA 212(a)(1)(ii) if the vaccine protects 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. The ACIP recommends the COVID-19 vaccine for the general U.S. population, and because the COVID-19 vaccine protects against, a disease that "has the potential to cause an outbreak" and/or "is in the process for elimination in the United States," the vaccination requirement for immigrant visa and adjustment of status applicants is triggered. On August 16, 2021, CDC updated the Technical Instructions for Panel Physicians and Civil Surgeons ("TIs"), which outline in detail the scope of the medical examination required for applicants for adjustment of status or an immigrant visa, to

include vaccinations against SARS-CoV-2 ("COVID-19"), effective October 1, 2021. Individuals who are subject to the COVID-19 and other vaccination requirements may be eligible for a waiver without any additional application in certain circumstances, e.g., if the vaccination is not medically appropriate or not routinely available; and may apply for a waiver under other circumstances, including if it is contrary to the applicant's religious beliefs or moral convictions.

2. What business purpose is the information gathered going to be used for?

The purpose of the medical examination required under INA § 221(d) is to determine whether the applicant has a medical condition that renders the applicant ineligible to receive a visa or a medical condition which, although not constituting a specific excludable condition, represents a departure from the normal health or well-being that is significant enough to interfere with the applicant's ability to care for himself, prevent attendance at school or work, or requires extensive medical treatment or institutionalization in the future. Under INA § 212(a)(1)(A)(ii) a noncitizen who seeks admission into the United States as an immigrant, or who seeks adjustment of status to lawful permanent residence, is inadmissible into the United States if the noncitizen is unable to present documentation of having received vaccinations against vaccine-preventable diseases recommended by the ACIP. The Department implements the medical examination requirements through various forms that make up two information collections: DS-2054, DS-3030, DS-3025, DS-3026 (OMB Control No. 1405-0113) and DS-7794 (OMB Control No. 1405-0230): Electronic Medical Examination for Visa Applicant.

In both cases, a panel physician, in accordance with TIs issued by the CDC, performs the medical examination of the applicant and completes the forms. The medical finding by the panel physician or the CDC, if referred to that agency, is binding on the consular officer in adjudicating the noncitizen's eligibility for a U.S. visa. The information requested on the medical forms is limited to the result of any diagnostic tests required for the diagnosis of the diseases identified as communicable diseases of public health significance and other evaluations identified as necessary to confirm a medical ineligibility under INA § 212(a)(1), 8 U.S.C. § 1182.

By law only immigrant visa applicants are subject to the vaccine requirements in INA § 212(a) (1)(A)(ii); however, applicants for the K nonimmigrant visas are strongly encouraged to complete all required vaccines before traveling to the United States. The vaccine worksheet is used to record the complete vaccine history for all such applicants. This helps ensure the applicant has the proper vaccines as the time of adjustment and has a complete vaccine record for subsequent use after the applicant is admitted to the United States.

3. Is this collection able to be completed electronically (e.g. through a website or application)?

Currently certain nonimmigrants, diversity visa, and follow-to-join refugees and asylum applicants require paper medical exam forms, including the DS-3025 Vaccine Documentation Worksheet. Additionally, in the unlikely event the DS-7794, Electronic Medical Examination for Visa Applicant (OMB Number 1405-0230) should experience a prolonged outage, panel physicians may be authorized by the Department to utilize and submit the paper based medical forms.

4. Does this collection duplicate any other collection of information?

This information is also collected in electronic form under OMB Control number 1405-0230.

5. *Describe any impacts on small business.*

The information collection does not involve small business or other small entities.

6. What are the consequences if this collection is not done?

This information collection is essential for determining the eligibility of noncitizens seeking an immigrant visa, nonimmigrant visa, or refugee status to enter the United States. It is not possible to collect the information less frequently since up-to-date medical information, including vaccination for COVID-19 or an exemption to or waiver of the vaccination requirement is necessary to determine the eligibility of the applicant.

7. Are there any special collection circumstances?

No special circumstances exist.

8. Document publication (or intent to publish) a request for public comments in the Federal Register

The Department will publish a notice in the *Federal Register* soliciting public comments on the proposed changes to the DS-3025, Vaccine Documentation Worksheet.

9. Are payments or gifts given to the respondents?

No payment or gift is provided to respondents.

10. Describe assurances of privacy/confidentiality

Visa applicants will be informed that the information obtained through the panel physician as part of the collection will be used to determine eligibility under immigration law. In the case of refugees, applicants will be informed that the information obtained through the panel physician is a part of the collection as required under INA § 412(b)(4) and (5), 8 U.S.C. § 1522(b)(4) and (5). In accordance with INA § 222(f) information obtained from applicants in the visa process is considered confidential and can be disclosed in certain circumstances enumerated in statute, including for use in the formulation, amendment, administration, or enforcement of the immigration, nationality, and other laws of the United States.

11. Are any questions of a sensitive nature asked?

Yes, the medical forms collect health and medical information of a sensitive nature. The questions in these information collections are designed to solicit the medical information necessary to determine whether an applicant is eligible for a visa under INA § 212(a)(1). This information collection is also used to determine whether refugees have medical conditions affecting the public and requiring treatment under INA § 412(b)(4)(B). Applicants will be advised that the information from the medical examination may be accessible to other U.S. government agencies having statutory or other lawful authority to use such information, including for law enforcement and immigration enforcement purposes.

12. Describe the hour time burden and the hour cost burden on the respondent needed to complete this collection

Approximately 690,742 noncitizens are annually subject to a medical examination. Of these, The Department expects 110,412 will submit paper forms. While only immigrant visa applicants are required to get vaccines as a condition of their visa, K visa applicants and non-immigrant visa applicants may be asked if they have received a COVID-19 vaccination. A panel physician completes an examination for each applicant.

The estimated amount of time it takes for a medical professional to complete the medical exam is one hour. One hour is therefore a reasonable estimate for the time it will take to complete each instance of collection. Therefore, the annual hour burden to respondents is estimated to be 110,412 hours (110,412 respondents x 1 hour). Based on the average U.S. hourly wage of \$27.07\dagger the weighted wage hour cost burden for this collection is approximately \$4,483,279.26. This is based on the calculation of 1 hour x \$27.07 (average hourly wage) x 1.5 (weighted wage multiplier, which adjusts the average hourly wage to a "fully loaded" salary, including, e.g., benefits, etc.) x 110,412 respondents = \$4,483,279.26. The Department does not believe the COVID-19 vaccination requirement will add any additional time for the medical professional to complete the medical exam.

13. Describe the monetary burden to respondents (out of pocket costs) needed to complete this collection.

Based on an estimate of the average cost of medical examinations administered by panel physicians worldwide (\$100), and the number of applicants per year (4,483,279.26), the estimated annual cost burden is \$11,041,200. $$100 \times 110,412$ applicants = \$11,041,200). Given the wide variance in costs for providing different versions of the COVID-19 vaccine in different countries, the Department cannot provide any additional information on the cost to applicants at this time.

14. Describe the cost incurred by the Federal Government to complete this collection.

The Department estimates that the cost of this information collection to the Federal Government is on average, approximately \$149,056.20 per fiscal year. This estimate is based on the current hourly charge for the consular time from the Cost of Service Module ("CoSM") of \$135, multiplied by the number of hours required to review the application and number of respondents. The design of the form allows the consular officer to thoroughly review the form for an

¹ Source: Data from the U.S. Bureau of Labor Statistics' May 2020 National Occupational Employment and Wage Estimates for all occupations. https://www.bls.gov/oes/current/oes_nat.htm#00-0000

indication of medical ineligibly in a period time lasting no more than one minute. Therefore, 1/60 hours x \$135 CoSM x 110,412 respondents = \$149,056.20.

15. Explain any changes/adjustments to this collection since the previous submission

In response to revised CDC technical instructions for the administration of the medical examination, panel physicians will now be required to ask noncitizens subject to Department of State medical examinations if they have been vaccinated for COVID-19, and if so which vaccination they have received. This information will be recorded in a new "COVID-19" field on the DS-3035

16. Specify if the data gathered by this collection will be published.

A quantitative summary of all Department of State visa activities is published in the annual Report of the Visa Office. The Report of the Visa Office is an annual report providing statistical information on immigrant and nonimmigrant visa issuances by consular offices, as well as information on the use of visa numbers in numerically limited categories. The Visa Office currently has annual reports available from 2000 to 2019. The link to the website is: https://travel.state.gov/content/travel/en/legal/visa-law0/visa-statistics.html.

17. If applicable, explain the reason(s) for seeking approval to not display the OMB expiration date.

The Department will display the expiration date for OMB approval of the information collection.

18. Explain any exceptions to the OMB certification statement below.

The Department is not requesting any exception to the certification statement.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection does not employ statistical methods.