

Statement in Support of Application for Waiver of Inadmissibility under Immigration and Nationality Act

(OMB Control No. 0920-0006)

Expiration Date: 12/31/2023

**Request for OMB approval of a Reinstatement with Change of a Previously
Approved Information Collection**

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Supporting Statement A

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- **Goal of the study:** Goal of the collection is to provide CDC with adequate information to fulfill its responsibilities with regard to the processing of applications for waivers of inadmissibility on health-related grounds, specifically mental health disorders with associated harmful behaviors.
- **Intended use of the resulting data:** The intended use of the information is to review waiver applications for prospective immigrants to the United States. CDC assists DHS/USCIS in determining whether or not a prospective immigrant with a Class A mental health disorders with associated harmful behavior may be admitted into the United States.
- **Methods to be used to collect:** The information collected is required under U.S. immigration law and regulation. CDC form 4.422-1 is generated by CDC with Part I completed with information provided on the DHS/USCIS waiver form (I-601 or I-602), which includes the race/ethnicity of the applicant. Part II and III must be completed by the U.S. medical facility or specialist, and by the applicant and applicant's sponsor. The completed statement must be reviewed by CDC before an applicant is approved for a waiver.
- **The subpopulation to be studied:** The subpopulation includes applications for U.S. immigration who file a request for a waiver of health-related inadmissibility.
- **How data will be analyzed:** The data is only analyzed for program improvement purposes.

1. Circumstances Making the Collection of Information Necessary

The purpose of this submission is to request a Reinstatement with Change of the current OMB approval of the information collection "Statement in Support of Application for Waiver of Inadmissibility under Immigration and Nationality Act," (OMB No. 0920-0006), including standardized format for required evaluation report, that is set to expire 12/31/2023. CDC is requesting a 3-year approval to collect this on information.

This information collection is authorized under Section 212 of the Immigration and Nationality Act (8 USC Section 1182 (a)(1)(A)(iii)(I) and 1182 (a)(1)(A)(iii)(II)), amended as of September 30, 1996 (Attachment A1), as well as 42 Code of Federal Regulations part 34 (Attachment A2).

This information collection is related to waivers of inadmissibility on health-related grounds, specifically mental health disorders with associated harmful behavior. Information collected for waivers of other inadmissible health conditions is captured via I-601 or I-602 waiver forms administered by the Department of Homeland Security, therefore CDC is not requesting an information collection for those forms.

Background

Section 212 (a) of the INA states that aliens with specific health-related grounds are ineligible to receive visas and ineligible for admission into the United States. The conditions are listed in subsections as follows:

- (i) aliens who have a communicable disease of public health significance,
- (iii) (I) aliens who have a physical or mental disorder and behavior associated with the disorder that may pose, or has posed, a threat to the property, safety, or welfare of the alien or others; or
- (iii) (II) aliens who have had a physical or mental disorder and a history of behavior associated with the disorder, which behavior has posed a threat to property, safety, or welfare of the alien or others and which behavior is likely to recur or lead to other harmful behavior.

However, section 212(g) of the INA authorizes the Attorney General to waive certain Class A inadmissible health-related grounds which would allow an alien to overcome his/her inadmissibility (Attachment A3).

The Centers for Disease Control and Prevention (CDC) may provide consultation to the U.S. Department of Homeland Security for requests for waivers under Section 212(a)(1)(A)(i) or Section 212(a)(1)(A)(iii)(I) or (II), as indicated in the regulations (8 CFR 212.7 Waiver of certain grounds of excludability) (Attachment A3):

“the alien or the alien’s sponsoring family member shall submit a statement to the consular or Service office. The statement must be from a clinic, hospital, institution, school, or other specialized facility or specialist in the United States ... who will complete the evaluation and provide an evaluation report to the Centers for Disease Control and Prevention.”

Waiver requests under Section 212(a)(1)(A)(i) are processed on DHS’ forms I-601 and I-602. Waiver requests under Section 212(a)(1)(A)(iii)(I) or (II) are processed under CDC form 4.422-1 (Attachment C). Respondents to this data collection include U.S. medical facilities and specialists who complete Part II of CDC form 4.422-1 for waiver applicants based on physical or mental disorders and submit the appropriate evaluation report. Respondents also include the applicant or sponsoring family member who complete Part III of CDC form 4.422-1 (Attachment C).

CDC’s Division of Global Migration and Health (DGMH) works closely with the Department of Homeland Security (DHS)’s office of U.S. Citizenship and Immigration Services (USCIS) and Department of State (DOS)’s consular offices. To obtain the waiver, the alien follows the subsequent steps:

- a) The alien contacts the consular officer or DHS/USCIS officer to obtain the DHS/USCIS form I-601 (for immigrants) or I-602 (for refugees).
- b) The alien completes form I-601/I-602 and files with DHS/USCIS.
- c) The receiving DHS/USCIS office in the U.S. sends the medical documents and the I-601/I-602 form to CDC/DGMH for review.
- d) CDC/DGMH reviews the medical information submitted to determine if the applicant meets the medical requirements for a waiver under Section 212(a)(1)(A)(iii)(I) or (II) as outlined above.
- e) If the request for a waiver is under Section 212(a)(1)(A)(iii)(I) or (II), DGMH issues and completes Part I of CDC Form 4.422-1 as the Reviewing Official.

- f) CDC then sends the form back to the requesting DHS/USCIS office. As applicable, that office, in turn, forwards CDC Form 4.422-1 to the applicant's sponsor in the U.S. for completion.
- g) The applicant's sponsor locates a medical facility or specialist in the U.S. who will agree to perform the applicant's initial evaluation. As applicable, the physician completes Part II of CDC form 4.422-1, indicating that he/she will indeed perform the applicant's initial evaluation after the applicant admission to the U.S. The applicant (or applicant's sponsor) completes, as applicable, Part III of CDC form 4.422-1, affirming that the applicant will report to the specialist or facility that completed Part II.
- h) Completed forms are returned to CDC/DGMH for final review. If CDC approves, they will let DHS/USCIS know they support the waiver. DHS/USCIS makes the final decision on whether or not a waiver will be granted. Once the waiver is approved by DHS/USCIS and the applicant is admitted to the United States, the evaluation occurs.

This information collection is authorized under Section 212 of the Immigration and Nationality Act (8 USC Section 1182 (a)(1)(A)(iii)(I) and 1182 (a)(1)(A)(iii)(II)), amended as of September 30, 1996, as well as 42 Code of Federal Regulations part 34.

2. Purpose and Use of Information Collection

HHS/CDC Part 34 regulations require that all immigrants and refugees coming to the United States be screened for physical and mental disorders with associated harmful behaviors and substance abuse and addiction. CDC uses the information collected in 0920-0006 to review waiver applications for prospective immigrants and refugees to the United States. CDC assists DHS/USCIS in determining whether or not a prospective immigrant or refugee with a Class A health designation, specifically those mental health disorders with associated harmful behavior, may be admitted into the United States.

DHS/USCIS regulations require that a statement be furnished from a U.S. medical facility or specialist agreeing to see the waiver applicant for an initial evaluation after admission to the U.S. The statement is reviewed by CDC and submitted to the DOS consular or DHS/USCIS officer before the applicant is approved for a waiver. The initial report furnished by the U.S. specialist or facility is submitted to DGMH to confirm that the individual reported to the facility or specialist and that an initial evaluation was done.

The information collected includes personal and identifiable information on the alien; it also includes a medical evaluation of the alien. The primary purpose of the forms is to maintain adequate records on waiver applicants, thereby complying with the regulations set forth by DHS/USCIS. The information in identifiable form includes name, address, date of birth, DHS/USCIS file number, and medical information.

The methods outlined in this supporting statement have been routine procedure for several years and are a requirement in order for CDC to acquire sufficient information to review the facts of a request for a waiver. The information collection requirement is codified in regulation and has been communicated by

DHS and CDC to respondents for the duration of CDC's involvement with the review of requests for waivers.

CDC is updating the name, signature, title and address of US public health service reviewing official field on the information collection form 4.422-1 because the previously listed individual has retired and no longer completes this action. The name, signature, title and address will be updated to reflect the current Branch Chief of the Immigrant Refugee and Migrant Health Branch in DGMH.

CDC's estimate of burden over the last three years for form 4.422-1 has been adequate to accommodate the number of requests for waivers received by the agency on an annual basis. To date, the respondent and authorized government user experience has been adequate and without complaint. CDC does not request any change to the burden for form 4.422-1.

3. Use of Improved Information Technology and Burden Reduction

The amount of information collected is limited to that necessary for CDC to carry out its public health responsibilities as required by law. Because CDC relies on DOS and USCIS for coordination of this information collection, CDC does not currently use any IT in this information collection, however if this changes, CDC will submit an explanation to OMB for approval.

4. Efforts to Identify Duplication and Use of Similar Information

No similar information is available. Reports relate to aliens who are admitted to the U.S. with an approved waiver of grounds of inadmissibility. Regulations require reports to be furnished to the Director, Division of Global Migration and Health, Centers for Disease Control and Prevention, Atlanta, Georgia. No other component of the Public Health Service is involved in the medical examination of aliens and waiver procedures.

5. Impact on Small Businesses or Other Small Entities

Collection of information may or may not involve small business. The applicant's family can choose the U.S. medical facility or specialist that they wish to perform the follow-up evaluation.

The information requested has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

Less frequent data collection would not conform to the regulations. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Notice was published in the *Federal Register* on November 3, 2023, Vol. 88, No. 212, page 75593 (Attachment B). CDC received three comments related to this notice (Attachments E1-E3) and responded to two of the comments. CDC did not provide a response the third comment (Attachment E3) since it was submitted anonymously.
- B. DHS provides guidance concerning its regulations pertaining to the health-related grounds of inadmissibility and the waiver requirements to overcome the inadmissibility. CDC's contact person for this is Laura Rakuljic, Residence & Naturalization Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW, Washington, DC 20529, 202-272-9399.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Act applies only to U.S. citizens and lawfully admitted aliens. However, in a previous submission, the HHS Privacy Act Advocate indicated that there was no legal barrier to extending Privacy Act protection to the respondents in this information collection request. Therefore, CDC's judgment has been that the Privacy Act is applicable to this data collection (Attachment F). The applicable Systems of Record Notice is 09-20-0102: Alien Mental Waiver Program; 51 FR 42449 11/24/86

The personal and identifiable information on the alien is filed and retrieved by name and date and country of birth. In many cases, the alien registration number given to the alien by USCIS is also provided to DGMH for identification purposes.

DGMH considers the primary purpose of these forms to be to maintain adequate records on waiver applicants, thereby complying with the regulations set forth by DHS/USCIS. Also, Section 237 of the INA was amended to subject an alien to deportation if the Secretary of Health and Human Services certifies that the alien has failed to comply with the terms, conditions, and controls imposed by the waiver. If an alien is admitted to the U.S. with an approved waiver and fails to comply with the terms, conditions, and controls imposed by receiving a waiver, CDC could share this information with the DHS/USCIS.

The currently approved information collection could have an effect on a respondent's privacy. As described in the System of Records Notice 09-20-0102: Alien Mental Waiver Program, CDC maintains several safeguards to prevent a breach of information security. Access to collected information is granted to only a limited number of personnel, i.e., program manager and immediate support members, as authorized by the system manager to accomplish the stated purposes for which the data in this system have been collected. Information is kept in locked cabinets in locked rooms, 24-hour guard service in buildings, personnel screening of visitors, electronic anti-intrusion devices in operation at the CDC

Roybal Campus and Federal Records Center. Data bases are kept secure with the use of secure passwords and key card access. Users of individually identified data protect information from public scrutiny, and only specifically authorized personnel may be admitted to the record storage area. CDC employees who maintain records are instructed to check with the system manager prior to making disclosures of data.

Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual. In the event of litigation where the defendant is: (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Department of Justice has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected. CDC is authorized to share information on aliens with the Social Security Administration to determine eligibility for benefits, pursuant to Section 1631 (e) of the Social Security Act as amended by Public Law 103-296, or as otherwise provided for in the Social Security Act.

DHS/USCIS regulations require that a statement be furnished from a U.S. medical facility or specialist agreeing to see the waiver applicant for an initial evaluation after admission to the U.S. The statement is reviewed by CDC and submitted to the DOS consular or DHS/USCIS officer before the applicant is approved for a waiver. The initial report furnished by the U.S. specialist or facility is submitted to DGMH to confirm that the individual reported to the facility or specialist and that an initial evaluation was done.

Aliens with a Class A inadmissible condition must complete the waiver process if they wish to try and overcome their determination of inadmissibility. There is no separate consent form; however, the alien and/or alien's family member must sign Part III of CDC form 4.422-1 indicating compliance with conditions of waiver which include submission of the medical evaluation to CDC. Failure to comply with the terms, conditions, and controls of the waiver of inadmissibility may subject the alien to deportation under the INA. This advisory is printed at the bottom of CDC form 4.422-1. Additionally, the applicant signs the I-601/I-602 waiver form. This waiver form, provided by USCIS, allows for the release and sharing of information as needed. CDC relies on USCIS for the administration and approval of the waiver for the alien applicant, so this consent covers the CDC process of reviewing the medical information on the waiver.

The personal and identifiable information on the alien is filed and retrieved by name and date and country of birth. In many cases, the alien registration number given to the alien by USCIS is also provided to DGMH for identification purposes.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

IRB review is not required for this information collection (Attachment D).

Sensitive Questions

The report furnished is a medical evaluation of the alien. Information of a sensitive nature may be voluntarily furnished by the specialist or facility in the report. As part of the waiver procedure, the alien is aware that the medical evaluation will be furnished to DGMH and that because the report is an evaluation of his/her physical/mental disorder, sensitive information may be included in the report that is forwarded to CDC. This information is required in order for CDC to fully evaluate the application.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

All respondents are U.S. medical facilities or specialists, and they are the only respondents allowed to provide information on the forms.

Completion of CDC form 4.422-1 is required for CDC to review waiver applications for prospective immigrants and refugees to the United States. Each year approximately 200 immigrant visa or refugee applicants request a Waiver of Inadmissibility. Therefore, CDC estimates there could be 200 responses, which CDC estimates would require only 10 minutes of a medical facility or specialist's time since much of the information has already been obtained through the initial medical exam and waiver request from DHS.

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Physician	CDC 4.422-1	200	1	10/60	33
Total					33

B. Estimated Annualized Burden Costs

The annualized cost to respondents is an estimate since different U.S. healthcare providers have different rates and the applicant must pay for any charges involved in the evaluation. Some healthcare providers, e.g., regional medical centers, are mandated by State law to provide services if the applicant resides in their area of jurisdiction. Using an average physician's wage of \$114.76 per hour (29-1229 Physicians, All Other)*, the calculated annualized cost to respondent is \$3,787.08.

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Physician	CDC Form 4.422-1	33	\$ 114.76	\$3,787.08
Total				\$3,787.08

* <https://www.bls.gov/oes/current/oes291228.htm>

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

The respondents must send the forms and other documents for evaluation to CDC. CDC estimates that the paper mailing cost per respondent is about \$15 per year, with a total annual cost to respondents up to about \$3,000.

14. Annualized Cost to the Government

The annual cost to the government for executing this information collection is composed of personnel time and services, and materials processing effort. The costs are outlined below.

Estimated Annualized Cost to the Government per Activity	
Cost Category	Estimated Annualized Cost
Professional services provided by psychiatric consultant	\$52,634
CDC Professional and Clerical staff	\$20,000
Total annualized cost to the Federal government	\$72,634

15. Explanation for Program Changes or Adjustments

CDC is updating the name, signature, title and address of US public health service reviewing official field on the information collection form 4.422-1 because the previously listed individual has retired and no longer completes this action. The name, signature, title and address will be updated to reflect the current Branch Chief of the Immigrant and Refugee Health Branch in DGMH.

There is no change to total burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for publishing any information obtained either on the waiver forms or from the reports furnished to CDC.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A1: 8 USC Section 1182 (a)(1)(A)(i), 1182 (a)(1)(A)(iii)(I), 1182 (a)(1)(A)(iii)(II)

Attachment A2: 42 CFR Part 34 Medical Examination of Aliens

Attachment A3: 8 CFR 212.7 Waiver of certain grounds of excludability

Attachment B: 60 day Federal Register Notice

Attachment C: CDC form 4.422-1

Attachment D: CDC Non-Research Determination

Attachment E1: Public Comment and Response #1

Attachment E2: Public Comment and Response #2

Attachment E3: Public Comment #3

Attachment F: Privacy Impact Assessment