Supporting Statement A
Medical Standards and Certification, OMB No. 2120-0034

CHANGES IN THIS SUBMISSION

- In October of 2018, Congress passed the FAA Reauthorization Act (Public Law 115-254). Section 318 of Public Law 115-254 directed the Administrator to revise 14 CFR 61.3(c) (relating to second-class medical certificates) to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft. In November of 2021, the FAA issued *Medical Certification Standards for Commercial Balloon Operations*, a notice of proposed rulemaking (NPRM) in response to the statutory directive. The NPRM proposed extending the requirement of second class medical certificates to commercial balloon pilots engaged in certain commercial balloon operations.

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The Secretary of Transportation collects this information under the authority of 49 U.S.C. 40113; 44701; 44702; 44703; and 44709. Title 14 of the Code of Federal Regulations (14 CFR), parts 61 and 67, sets forth specific operational and medical requirements for pilot certification. The FAA is updating this information collection to include commercial balloon pilots under those pilots required to hold a first or second class medical certificate, as mandated by Section 318 of the FAA Reauthorization Act of 2018 (P.L 115-254). The FAA collects specific medical information to determine whether applicants are medically qualified to perform the duties associated with the class of airman medical certificate sought. This collection of information supports the DOT Strategic Goal on safety.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Individuals seeking to exercise certain pilot privileges are required to obtain a FAA medical certificate per 14 CFR §61.3(c), §61.23(a), and §67.4. The collection is mandatory to be reported on occasion (as needed) based on the duration of the three classes of medical certificates as specified in 14 CFR §61.23(a) and will vary among respondents. The FAA collects this medical information only when an individual initially applies for or renews a FAA medical certificate. All applications and supporting documentation received are for decision-making and recordkeeping purposes.

Respondents provide private medical information in order to demonstrate that they meet FAA medical standards; their applications contain personal identifiable information (PII) and protected health information (PHI). The application contains questions regarding the individual's current and past medical history such as the usage of medication, recent visits to a health professional, etc. It is anticipated that the information collected will be disseminated to Aviation Medical Examiners (i.e. physicians designated by the FAA) through an automated system or used to support publicly disseminated information. The FAA Office of Aerospace Medicine will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with FAA

standards for confidentiality, privacy, and electronic information. See response to Question 10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines.

The FAA assigns a unique Applicant Identification number (called an Applicant ID) to each respondent at the time of their initial application. Renewal applicants maintain the same Applicant ID as their unique identifier for the lifecycle of their applications with the FAA.

Following is a brief description of the purpose of this medical information collection:

FAA Form 8500-8, Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate: Applicants complete this form online to make application for an FAA medical certificate. FAA-designated Aviation Medical Examiners (AMEs) perform a medical examination and, based on the applicants' input, work with Agency physicians to assess an applicant's medical fitness.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

The FAA Office of Aerospace Medicine continually seeks ways to use technology to reduce burden on medical certificate applicants. The FAA MedXPress system, which was launched in 2007, is used exclusively on-line to submit the FAA Form 8500-8 (see "Notice of Intent To Discontinue Use of Paper Applications for Airman Medical Certification," 77 FR 13967; March 8, 2012). Anyone requiring an FAA medical certificate needs to electronically complete the medical history portion of FAA Form 8500-8 online and transmit it to an Aviation Medical Examiner (AME).

Information entered into MedXPress is transmitted to the FAA and is available for the AME to review at the time of the applicant's medical examination. AMEs are required to electronically transmit FAA Form 8500-8 to the FAA Aerospace Medical Certification Division for processing via the Aeromedical Certification Subsystem (AMCS), https://www.faa.gov/other_visit/aviation_industry/designees_delegations/designee_types/ame/amcs. This system improves the process by reducing paperwork, eliminating errors of omission on the application, enabling transmission 24-hours-a-day, and allowing the FAA to review applications shortly after transmission from the AME. Since Form 8500-8 is transmitted electronically through MedXPress, it may not be printed and/or sent by mail.

The results of the information collection are protected by the Privacy Act of 1974; however, general metrics regarding the number of applications submitted per year can be assessed by request.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

Form 8500-8 was designed to assist the FAA in evaluating the medical fitness of applicants for FAA medical certification. The FAA Office of Aerospace Medicine uses this form to collect an applicant's personal medical information and is not available elsewhere.

5. If the collection of information involves small businesses or other small entities, describe the methods used to minimize burden.

This information is collected from individuals who are part of the small business community, in some cases. However, the economic impact of the rule is insignificant. Nevertheless, the FAA continues to take steps to minimize their burden by consolidating and streamlining information for FAA-designated Aviation Medical Examiners (AMEs) online (https://www.faa.gov/other_visit/aviation_industry/designees_delegations/designee_types/ame).

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

The collection of an applicant's medical information complies with pertinent operational provisions of 14 CFR Part 61 and medical provisions of 14 CFR Part 67. For example, § 61.3(c) sets forth requirements for FAA certificates, including medical certificates, and 61.23(d) sets forth the duration of the three classes of FAA medical certificates. Part 67 Subpart A sets forth specific application standards and the actual performance standards (e.g., medical, physical, mental, etc.) for FAA medical certificate applicants. Applicants not complying with these standards would be in violation of the regulations. Reducing the burden, conducting the collection less frequently, or not conducting the collection at all would impair the ability of the FAA to determine if an individual is medically fit to fly and thereby decrease the safety of the National Airspace System, and would require regulatory amendment of existing minimum standards.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

- **Requiring respondents to report information to the agency more often than quarterly;**
  - N/A
- **Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
  - N/A
- **Requiring respondents to submit more than an original and two copies of any document;**
  - N/A
- **Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**
  - N/A
- **In connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
  - N/A
- **Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
  - N/A
- **That includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or,**
  - N/A

- **Requiring respondents to submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**
    - N/A

There are no special circumstances associated with this information collection. This information collection is consistent with the guidelines in 5 CFR 1320.5(d)(2).

8. Provide information on the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

A Federal Register Notice published on August 13, 2019 (84 FR 40125) solicited public comment. The FAA received 13 comments - 12 from the Aircraft Owners and Pilots Association (AOPA) and one from a private citizen. The Office of Aerospace Medicine reviewed the comments received. A list of the comments received and the FAA's response are included in the renewal package submitted to OMB and summarized below.

AOPA's 2019 comments focused on FAA Form 8500-8, Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate. The organization asserted that the FAA had made changes to the form that did not benefit the flying public, increased burdens, and are not aligned with National Transportation Safety Board (NTSB) and Government Accountability Office (GAO) recommendations. .

In 2015, the FAA had solicited public comments for the revision of the 2120-0034 information collection, and more specifically revisions to Form 8500-8. No comments were received from the public after the 60- and 30-day comment periods. The FAA then requested and received OMB approval for several changes based on input from the GAO. Due to resource constraints, the FAA was not able to complete all the changes that received OMB approval. Some of the revisions addressed questions that AOPA believed were still misleading or unclear in 2019. However, the FAA did develop ways to improve certain questions on the form. For instance, the addition of drop down instructions helps the applicant to identify medical history and possible underlying conditions.

AOPA also commented in 2019 on the burden associated with completing Form 8500-8. The organization claimed that the form takes longer than the estimated 1.5 hours to complete because airmen have to gather information before they can complete the form. The current burden estimate of 1.5 hours includes all necessary time to review instructions, compile necessary materials, and to complete the form itself.

AOPA's 2019 comments stated that the FAA did not consider the suggestions made by the NTSB and a 2014 GAO report when revising the medical certification application. However, the purpose of the 2016 request to revise the information collection was to incorporate suggestions provided by the GAO. Making changes to Form 8500-8 will increase accuracy and completeness of the medical information

submitted by applicants. As previously mentioned, budget constraints have prevented the FAA from implementing many of the revisions approved by OMB.

The one comment received in 2019 from a private citizen was also about Form 8500-8. The comment proposed the discontinuation of the Electrocardiogram (EKG) and reduction in the frequency of colorblindness tests for Class I medical certification. The individual who submitted the comment believed that both the EKG and tests for colorblindness are costly and only used by doctors as an indicator for medical conditions. However, the law mandates the frequency and use of certain medical tests for aerospace medical certification. The comment was outside of the scope of the Paperwork Reduction Act request to renew information collection 2120-0034.

On November 18, 2021, the FAA published an NPRM (86 FR 64419) to include commercial balloon pilots under those pilots required to hold a first or second class medical certificate, as mandated by Section 318 of the FAA Reauthorization Act of 2018 (P.L 115-254). The NPRM solicited comments from the public regarding the need for information collection associated with the requirement for commercial balloon pilots to hold a second class medical certificate. The FAA did not receive any comment directly related to information collection. The Office of Aerospace Medicine's collaboration with stakeholders and efforts to improve the Medical Certification process have continued separately from the PRA process. These efforts will inform future requests to revise this package, which will be fully coordinated with the FAA PRA Office, OST, and OMB. The only change to this ICR is the expansion of applicability, as mandated by Congress, to a narrowly-defined group of aviation operators not previously required to obtain an FAA medical certificate.

9. Explain any decisions to provide payments or gifts to respondents, other than remuneration of contractors or grantees.

No payment or gifts are provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for assurance in statute, regulation, or agency policy.

The information collected from FAA Form 8500-8 becomes part of the Privacy Act System of Records DOT/FAA 847, "Aviation Records on Individuals," [DOT/FAA 847] and is provided the protection outlined in the description of the system as published in the Federal Register.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

No information regarding sexual behavior or religious belief is collected. Applicants must respond to medical questions on this FAA Form, so the FAA can make informed medical certification determinations.

12. Provide estimates of the hour burden of the collection of information. The statement should:

REPORTING							
Form #	**# of Respondents**	**# of Responses per respondent**	**Total # of responses**	**Time per response (hrs)**	**Total burden (hrs)**	**Cost per Hour**	**Total Cost per year**
8500-8	2,277	1	2,277	1.5	3,415.5	$31.50[1]	$107,588

The Office of Aerospace Medicine is expecting about 2,300 balloon pilots to provide information as part of OMB Control 2120-0034. Pilots are required to submit the form as needed for new medical certification or renewals. The public burden to complete the forms is approximately 3.4K hours annually.

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information.

Once the information on FAA Form 8500-8 is collected, respondents must receive a medical examination in order to be certificated to exercise commercial balloon pilot privileges. The average fee for a basic medical examination is estimated at $150. The total cost for medical exams in the first year is as follows:

$150 x 2,277submissions of Form 8500-8 = $ 341,550

14. Provide estimates of annualized costs to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

The total costs to the FAA to implement the requirement for commercial balloon pilots to hold a second-class medical certificate is the sum of the costs for FAA review and processing of MedXPress applications, review of special issuances, and review of National Driver Register (NDR) information associated with certain applications. The mid-estimated annualized cost to the Federal Government to implement the final rule is $285,910 at a 7 percent discount rate.

The FAA would incur costs associated with reviewing and processing applications submitted through MedXPress. It costs the FAA about $30 (about half an hour of a staff earning $58 an hour) to review and process each application through MedXpress. Approximately 10% of applicants would require special issuance, because they do not initially qualify for a second class medical certification. It costs about $126 (about 1.8 hours of a staff making $70 an hour) to review a special issuance. The FAA estimates there is roughly a 3% of applicants require additional review and investigation, which requires NDR data. The FAA estimates that it takes approximately 40 hours of additional review time by a special agent, earning $60 an hour, for each applicant that is flagged through the NDR database. Thus, each submission that requires further investigation would cost about $2,407. First year costs are calculated below:

[1] The opportunity cost for a balloon pilot to fill out a MedXPress.

2,277 applicants x 0.51 hours x $58 = $67,354
2,277 applicants x 10% x 1.8 hours x $70 = $28,690
2,277 applicants x 3% x 40 hours x $60 = $163,944

15. Explain the reasons for any program changes or adjustments.

In October of 2018, Congress passed the FAA Reauthorization Act (Public Law 115-254). Section 318 of Public Law 115-254 directed the Administrator to revise 14 CFR 61.3(c) (relating to second-class medical certificates) to apply to an operator of an air balloon to the same extent such regulations apply to a pilot flightcrew member of other aircraft. In November of 2021, the FAA issued *Medical Certification Standards for Commercial Balloon Operations,* a notice of proposed rulemaking (NPRM) in response to the statutory directive. The NPRM proposed extending the requirement of second class medical certificates to commercial balloon pilots engaged in certain commercial balloon operations.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish this information for statistical or other purposes.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons why display would be inappropriate.

We continue to seek approval not to display the expiration date on FAA Form 8500-8. Displaying the expiration date has caused confusion for respondents, for our nearly 2000 FAA AME designees, and for FAA IT program personnel who tend to associate the static date carried on the form for the currency of an applicant's medical information when there is no correlation. Further, as the information is collected through the MedXpress online system, applicants are entering data into an electronic interface and not entering data directly onto the form.

18. Explain each exception to the topics of the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

There are no exceptions to the certification statement