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

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 uses three forms to collect specific medical certification 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 pilot privileges are required to obtain a FAA medical certificate per 14 CFR §61.3(c) 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 §61.3(d) 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 meet FAA standards; their applications contain personally identifying information (PII). The application contains questions regarding medical history, 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. public 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 Pathology Index number (called a PI#) to each respondent's application. Renewal applicants maintain the same PI# 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 8500-7, Report of Eye Evaluation: Applicants who do not meet distant visual acuity standards and who desire an Authorization for Special Issuance of a Medical Certificate must submit FAA Form 8500-7 for evaluation and determination by FAA physicians.

FAA Form 8500-8, Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate: Applicants complete this form 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.

FAA Form 8500-14, Ophthalmological Evaluation for Glaucoma: Applicants with glaucoma must submit FAA Form 8500-14 so that FAA physicians can make determinations regarding permissible operational flight activities commensurate with their medical condition and public safety.

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 to electronically complete the medical history portion of FAA Form 8500-8 online and transmit it to an Aviation Medical Examiner (AME). Approximately 75% of FAA Forms 8500-7 and -14 are submitted by mail, while 25% are submitted electronically through MedXPress.

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 Civil Aerospace Medical Institute/Aerospace Medical Certification Division for processing via the Aeromedical Certification Subsystem (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 Office of Aerospace Medicine is currently testing and refining an enhanced, relational database that will encompass all of our various systems to improve efficiency.

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.

FAA Forms 8500-7 and -14 are available on line in .pdf fillable format at the FAA Forms website.

Form 8500-7: <u>https://www.faa.gov/forms/index.cfm/go/document.information/documentID/</u>185784

Form 8500-14: <u>https://www.faa.gov/forms/index.cfm/go/document.information/documentID/</u> 185785

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.

Forms 8500-7, -8, and -14 were designed to assist the FAA in evaluating the medical fitness of applicants for FAA medical certification. The FAA Office of Aerospace Medicine uses these forms to collect an applicant's personal medical information and are not available elsewhere.

The FAA Flight Standards Service uses a similar form entitled "Comprehensive Medical Examination Checklist (04-17), FAA Form 8700-2 which looks similar to FAA Form 8500-8 but is not a duplicate. FAA Form 8700-2 is used for a different purpose and Congress mandated its fields. The FAA Extension, Safety, and Security Act of 2016 (Pub. L. 114–190) (FESSA) was enacted on July 15, 2016. Section 2307 of FESSA, Medical Certification of Certain Small Aircraft Pilots, directed the FAA to "issue or revise regulations to ensure that an individual may operate as pilot in command of a covered aircraft" without having to undergo the medical certification process under 14 CFR part 67 (requiring the 8500-8 application). (*See* Section 2307 (a)(7) and 14 CFR §68.7.)

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

This information is collected solely from individuals and will not involve small businesses or small entities.

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 decrease the safety of the National Airspace System and would require regulatory amendment of existing minimum standards. Further, it would decrease the safety of the National Airspace System.

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;

 $\boldsymbol{0} \quad N/A$

• Requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;

o N/A

• Requiring respondents to submit more than an original and two copies of any document;

o N/A

• Requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;

o 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;

0 N/A

• Requiring the use of a statistical data classification that has not been reviewed and approved by OMB;

o 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,

o 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.
 - **o** 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.

AOPA's comments focused on FAA Form 8500-8, Application for Airman Medical Certificate or Airman Medical and Student Pilot Certificate. The organization asserts that the FAA made changes to the form that did not benefit the flying public, increased burdens, and are not aligned

with National Transportation Safety Board and the Government Accountability Office (GAO) recommendations. Aerospace Medicine reviewed the comments received and drafted a letter in response to AOPA's comments. A list of the comments received and the FAA's response are included in the renewal package and summarized below.

In 2015, the FAA 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. Some of the revisions included additional clarification on questions that AOPA believes is still misleading or unclear. Due to resource constraints, the FAA was not able to complete all the changes that received OMB approval. However, the FAA did develop ways to improve certain questions on the form. For instance, there is the addition of drop down instructions that help identify medical history and possible underlying conditions.

AOPA also commented on the burden associated with completing Form 8500-8. They claim 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 states that the FAA did not consider the suggestions made by 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 Agency received one comment from a private citizen also about Form 8500-8. The comment proposed the discontinuation of the Electrocardiogram (EKG) and reducing the frequency of colorblindness tests for Class I medical certification. The individual who submitted the comment believes that both the EKG and tests for colorblindness are costly and only used by doctors as an indicator for medical conditions. The law mandates the frequency and use of certain medical tests for aerospace medical certification. The comment is outside of the scope of the Paperwork Reduction Act request to renew information collection 2120-0034.

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 Forms 8500-7, -8, and -14 become 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 these FAA Forms so the FAA can make informed medical 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			
8500-7	6,000	1	6,000	0.25	1,500	\$40.62	\$60,930			
8500-8	396,104	1	396,104	1.5	594,156	\$40.62	\$24,134,617			
8500-14	6,000	1	6,000	0.25	1,500	\$40.62	\$60,930			
Summary (annual numbers)	408,104		408,104		597,156		\$24,256,477			

The Office of Aerospace Medicine is expecting over 408K airmen to provide information as part of OMB Control 2120-0034. Pilots are required to submit the forms as needed for new medical certification or renewals. The public burden to complete the forms is approximately 597.1K hours annually, approximately 24,483 more hours than previously reported.

Total burden (hrs) = SUM [# of Respondents x Hrs/App] = (12,000 x 0.25) + (396,104 x 1.5) = 594,156 hrs/year

According to the Bureau of Labor Statistics news release on Employer Costs for Employee Compensation, employee compensation averaged \$34.72 per hour worked.¹ This wage rate includes benefits. To account for indirect costs such as rent, utilities, and office equipment, the hourly wage rate is increased by 17 percent.² The estimated annualized cost to respondents for the hours of burden is \$24,256,477, approximately \$3,892,245 more than the previous reported.

¹ Bureau of Labor Statistics news release provided this compensation cost in its March 19, 2020 news release. For the last renewal, the FAA used \$35.56. There is a \$0.84 decrease for this filing. <<u>https://www.bls.gov/news.release/ecec.nr0.htm</u>>

² Source: Cody Rice, U.S. Environmental Protection Agency, "Wage Rates for Economic Analyses of the Toxics Release Inventory Program" (June 10, 2002), <u>https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0005</u>.

Total Cost = SUM [Total burden (hrs) x Cost/Hr] = (1,500 x \$40.62) + (594,156 x \$40.62) + (1,500 x \$40.62) = \$24,256,477 per year

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

Once the information is collected, respondents must receive a medical examination in order to be certificated to exercise pilot privileges. The average cost of a basic medical examination is estimated at \$117.00³.

\$117.00 x **396,104** submissions in CY 2019 = **\$46,344,168**

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.

Estimated annual cost to the Federal Government is \$4,778,252.

This cost is determined by estimating the time required for FAA personnel to review and process FAA Form 8500-8. All 8500-8 applications are electronically submitted. We estimate that approximately 75% of 8500-7 and 8500-14 forms are submitted via mail to the FAA; the remaining 25% are electronically submitted. Out of the 396,104 medical applications (8500-8) submitted in CY2019, 97.5% (386,469) resulted in the issuance of a medical certificate. We estimate that 75% of applications are electronically reviewed (no FAA work required). The remaining 25% will go to an FAA Legal Instruments Examiner (LIE). We estimate that 99,836 forms are submitted for these medical certificates at an average file processing time by an LIE of 15 minutes (0.25) each at an average wage of \$51.80⁴ per hour.

25% of **396,104** total submissions = **99,026 99,026** x 0.25 hours x \$51.80 per hour = **\$1,282,387**

After review by an LIE, approximately 50% will need review by a physician. We estimate that **49,513** of these forms are submitted to a physician at an average file processing time of 30 minutes (0.5) each at an average wage of \$141.21 per hour.

50% of **99,026** submissions reviewed by an LIE = **49,513 49,513** x 0.5 hours x \$141.21⁵ = **\$3,495,865**

\$1,282,387 + \$3,495,865 = \$4,778,252⁶

³ For reference to this cost estimate, see 82 FR 3161; January 11, 2017.

⁴ Note that for the previous renewal submission the FAA used a \$31.00 per hour wage for LIEs.

⁵ Note that for the previous renewal submission the FAA used an \$82.00 per hour wage for physicians.

 $^{^{6}}$ Note that the previous renewal submission used the formula of \$750,439 + \$1,985,227 = \$2,735,666. This submission has increased by \$2,042,586 due to wage increases, added benefits, and overhead costs.

Detail on the wages are shown in the table below:

weighted Average of Houriy wage for FAA Employees						
	Wages	Wages with	People			
	with	Benefits &	(Total)			
	Benefits	Overhead ⁷				
	а	b	С	b x c		
Legal instrument examiners	\$46.05 ⁸	\$51.80	51	\$2,642		
Regional Flight Surgeons	\$125.54 ⁹	\$141.21	9	\$1,271		
Senior Executive Physicians	\$125.54	\$141.21	3	\$424		
Civil Aerospace Medicine Institute (CAMI) Med	\$125.54	\$141.21	11	\$1,553		
Officers						
Civil Aerospace Medicine Institute (CAMI) Physicians	\$125.54	\$141.21	3	\$424		
		Total:	77	\$6,314		
Weighted Average Wage Rate = \$6,314 / 77						

Weighted Average of F	Iourly Wage for FAA	A Employees
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15. Explain the reasons for any program changes or adjustments.

In January 2016, the FAA Office of Aerospace Medicine submitted a package requesting to make revisions to Form 8500-8. In that package submission, FAA data indicated a total of 396,782 respondents; 378,782 for 8500-8, the general medical application; and 18,000 for FAA forms 8700-7 or 8700-14 for vision examinations.

In March 2017, an FAA rulemaking team submitted a package to revise the burden on FAA Form 8500-8 based on rulemaking action to codify Section 2307 Public Law Section 2307 of Public Law 114-190, the FAA Extension, Safety, and Security Act of 2016 (FESSA) into Title 14 of the Code of Federal Regulations (see 82 FR 3149; January 11, 2017.¹⁰) As part of that action, the team predicted the agency would see 179,498 fewer respondents. (They predicted 198,847 versus the 378,345 respondents actually received). Subtracting the 378,345 from the 198,847 respondents yields a difference of 179,498 respondents and this was not realized.

The FAA has not taken any action to increase burden on respondents since the last renewal and the projected revision associated with the rulemaking. For this renewal, the Agency actually received an increase in 8500-8¹¹ applications by 17,322: from 378,782 for CY 2015 to 396,104

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf

 ⁷ Source: Cody Rice, U.S. Environmental Protection Agency, "Wage Rates for Economic Analyses of the Toxics Release Inventory Program" (June 10, 2002), <u>https://www.regulations.gov/document?D=EPA-HQ-OPPT-2014-0650-0005</u>; 17% of wage (sans benefits) added for overhead
⁸ 2019 General Schedule (GS) Locality Pay Tables; GS-11 Step 5 plus locality pay for The REST OF UNITED STATES; https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/19Tables/html/RUS_h.aspx; plus fringe benefits:

⁹ SALARY TABLE NO. 2019-EX Level II; https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/19Tables/exec/ html/EX.aspx; plus fringe benefits: https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf

¹⁰ FESSA provided an alternative medical qualification option for applicants rather than the traditional (8500-8) medical certification process. The preamble to that rule stated the following: "For those individuals who elect to use this rule the FAA considers that they no longer possess any airman medical certificate. Thus, the FAA is making a corresponding change to information collection 2120-0034, Application for Airman Medical Certificate, to reduce the burden associated with that information collection." The FAA has seen approximately 40,000 (??) applicants under FESSA (see 2120-0770). This did not seem to have an effect on the 2120-0034 collection as predicted in the revision submission associated with the FESSA rule.

¹¹ Again, this includes only applicants seeking to qualify for FAA medical certification (under 14 CFR Part 67) and not the FESSA alternative (under 14 CFR Part 68) using FAA Form 8700-2, 2120-0770.

for CY 2019. As such, the difference in respondents should not be construed as increase in burden. It is simply a matter of the actual effect of the FESSA rule not being realized in the 2120-0034 collection. Further, an increase in applicants is not unusual; nor is it predictable from year to year. In addition, the salary rates of Legal Instrument Examiners, respondents, and Physicians also increased.

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 Forms 8500-8, 8500-7, and 8500-14. 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.

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.

2. **Recommendation:** To improve the applicants' understanding of the medical standards and the information required to complete FAA's medical certification process, the Secretary of Transportation should direct the Administrator of FAA to enhance the online medical-application system by clarifying instructions and questions on the medical application form and providing useful information to applicants.

Agency Affected: Department of Transportation

Status: Closed - Implemented

Comments: The Federal Aviation Administration (FAA) is responsible for overseeing the medical certification of more than 400,000 pilot candidates (candidate) annually to certify that they meet FAA's medical standards and are physically and mentally fit to fly. One of FAA's main tools to communicate medical standards directly to candidates, and to solicit medical information from them, is its online medical application system, MedXPress. In 2014, GAO reported that its analysis and medical experts' opinions indicate that FAA could improve its communication with applicants by making MedXPress more user-friendly and improving the clarity of the medical application form. Specifically, GAO found that MedXPress did not always align to leading practices in website content, navigation, and design identified by Usability.gov- a resource maintained by the U.S. Department of Health and Human Service for federal web designers. For example, MedXPress required candidates to scroll through a lengthy terms-of-service agreement; the instructions were unclear; and the application form contained unclear questions and terms a candidate could misinterpret. FAA could also improve the clarity of its medical application form by incorporating guidelines established in FAA's Writing Standards, including shorter sentences and paragraphs, active voice, and clear terms and questions. Consequently, GAO recommended that FAA enhance MedXPress by clarifying instructions and guestions on the form and providing useful information to candidates. In 2018, GAO confirmed that FAA had taken steps to improve MedXPress. Namely, FAA has updated MedXPress to provide drill-down information for questions that clarify questions and instructions and provide additional information to candidates. For example, FAA has clarified a question about medication usage to ask about prescription and non-prescription medications and instruct the candidate on how to complete the question. Similarly, the MedXPress medical history questions now include definitions of terms and examples of symptoms to provide additional information to candidates and help them more accurately answer questions. As a result, these FAA improvements could not only aid a candidate's understanding of the medical standards and requirements, but also may result in more accurate and complete information provided by candidates to better inform FAA's certification decisions.