SUPPORTING STATEMENT - PART A

COVID-19 Vaccine Screening and Immunization Documentation DHA Form 207 & Pediatric (5-11 years) COVID-19 Vaccine Screening and Immunization Documentation DHA Form 236 – OMB Control Number 0720-0068

Summary of Changes from Previously Approved Collection

- Added new collection instrument, DHA Form 236 for children ages 5-11 years.
- The estimated response time for the DHA Form 207 has decreased to 2 minutes.

1. <u>Need for the Information Collection</u>

Previously, DHA Form 207, "COVID-19 Vaccine Screening and Immunization Documentation" was approved for ages 12 years and older. The Defense Health Agency (DHA) is seeking approval for DHA Form 236, "Pediatric COVID-19 Vaccine Screening and Immunization Documentation" for those 5-11 years in order to document the clinical determination if the COVID-19 vaccine is appropriate for the specific patient.

Although both forms include the same questions, the COVID-19 Vaccine Working Group and DHA Patient Safety Office recommended a separate form in order to mitigate possible vaccination errors when administering to children ages 5-11. Both of these forms are authorized by Public Law 104-191, 10 U.S.C., Chapter Ch. 55, Medical and Dental Care; DHA Interim Procedures Memorandum (IPM) 20-004, "DoD Coronavirus Disease (COVID-19) Vaccination Program Implementation." The DHA Interim Procedures Memorandum 20-004 is the implementation guide for all Military Treatment Facilities (MTF).

2. <u>Use of the Information</u>

The DHA Form 207 is used to determine and document patient eligibility for a COVID-19 vaccination (ages 12 years and older). Respondents include Active Duty military members, Federal employees, beneficiaries, and contractors (based on their employment) who wish to receive the vaccine. In most cases, respondents are given paper copies of the form at an immunization clinic (on base or their local MTF). Respondents will complete Part I of the form and return it to a technician prior to receiving the vaccine. Part II and Part III of the form are completed by the screener and the vaccinator, respectively. No invitations or communications are sent to respondents. After vaccination the technician then enters the information on the form into the Electronic Medical Record (EMR)/IMR to document the vaccination.

On 2 November 2021, the Centers for Disease Control Advisory Committee on Immunization Practices approved the clinical recommendations for the use of select COVID-19 vaccines for pediatrics ages 5-11 years. The DHA Form 236 is used to determine pediatric patient clinical eligibility for receipt of a COVID-19 vaccination. Respondents are DoD beneficiaries parents or guardians of children receiving a vaccination. The process for completing this form is the identical to the DHA Form 207.

The DHA Form 236 is currently in use without an OMB Control Number and will be reported as a violation on the Information Collection Budget (ICB) report.

3. <u>Use of Information Technology</u>

35% of responses are collected electronically. More electronic submissions may occur in the future as DHA evaluates the efficacy of the screening and immunization process.

4. <u>Non-duplication</u>

The information obtained through this collection is unique and is not already available for use or adaptation from another cleared source.

5. <u>Burden on Small Businesses</u>

This information collection does not impose a significant economic impact on a substantial number of small businesses or entities.

6. <u>Less Frequent Collection</u>

The information collected through the DHA Form 207 and Form 236 is provided on the occasion that a patient, specifically beneficiaries or contractors, decide they want to receive the COVID-19 vaccination.

7. <u>Paperwork Reduction Act Guidelines</u>

This collection of information does not require collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2).

8. <u>Consultation and Public Comments</u>

Part A: PUBLIC NOTICE

A 60-Day Federal Register Notice (FRN) for the collection published on Friday, April 16, 2021. The 60-Day FRN citation is 86 FR 20130.

No comments were received during the 60-Day Comment Period.

A 30-Day Federal Register Notice for the collection published on Friday, June 25, 2021. The 30-Day FRN citation is 86 FR 33691.

Part B: CONSULTATION

No additional consultation apart from soliciting public comments through the Federal Register was conducted for this submission.

9. <u>Gifts or Payment</u>

No payments or gifts are being offered to respondents as an incentive to participate in the collection.

10. <u>Confidentiality</u>

A Privacy Act Statement is provided at the top of the forms.

A System of Record Notice (SORN) is required for this collection. EDHA 07, Military Health Information System is available at https://dpcld.defense.gov/Portals/49/Documents/Privacy/SORNs/DHA/ EDHA-07.pdf.

A Privacy Impact Assessment (PIA) is not required for this collection because PII is not being collected electronically.

Records Retention and Disposition Schedule: Temporary. Cut off upon last episode of patient care or last entry to the patient record is annotated. Delete/Destroy when 75 years old.

11. <u>Sensitive Questions</u>

No questions considered sensitive are being asked in this collection.

12. <u>Respondent Burden and its Labor Costs</u>

Part A: ESTIMATION OF RESPONDENT BURDEN

1) DHA Form 207

- a) Number of Respondents: 2,000,000
- b) Number of Responses Per Respondent: 2
- c) Number of Total Annual Responses: 4,000,000
- d) Response Time: 2 minutes
- e) Respondent Burden Hours: 133,333 hours
- 2) DHA Form 236

- a) Number of Respondents: 308,000
- b) Number of Responses Per Respondent: 2
- c) Number of Total Annual Responses: 616,000
- d) Response Time: 2 minutes
- e) Respondent Burden Hours: 20,533 hours
- 3) Total Submission Burden
 - a) Total Number of Respondents: 2,308,000
 - b) Total Number of Annual Responses: 4,616,000
 - c) Total Respondent Burden Hours: 153,866 hours

Part B: LABOR COST OF RESPONDENT BURDEN

- 1) DHA Form 207
 - a) Number of Total Annual Responses: 4,000,000
 - b) Response Time: 2 minutes
 - c) Respondent Hourly Wage: \$7.25
 - d) Labor Burden per Response: \$0.24
 - e) Total Labor Burden: \$966,666.67
- 2) DHA Form 236
 - a) Number of Total Annual Responses: 616,000
 - b) Response Time: 2 minutes
 - c) Respondent Hourly Wage: \$7.25
 - d) Labor Burden per Response: \$0.24
 - e) Total Labor Burden: \$148,866.67
- 3) Overall Labor Burden
 - a) Total Number of Annual Responses: 4,616,000
 - b) Total Labor Burden: \$1,115,533

Federal minimum wage was used to estimate labor burden as the hourly wages between beneficiaries and contractors vary extremely.

13. <u>Respondent Costs Other than Burden Hour Costs</u>

There are no annualized costs to respondents other than the labor burden costs addressed in Section 12 of this document to complete this collection.

14. <u>Cost to the Federal Government</u>

Part A: LABOR COST TO THE FEDERAL GOVERNMENT

- 1) DHA Form 207
 - a) Number of Total Annual Responses: 4,000,000

- b) Processing Time per Response: .25 hours
- c) Hourly Wage of Worker(s) Processing Responses : \$32.29
- d) Cost to Process Each Response: \$8.07
- e) Total Cost to Process Responses: \$32,290,000.00
- 2) DHA Form 236
 - a) Number of Total Annual Responses: 616,000
 - b) Processing Time per Response: .25 hours
 - c) Hourly Wage of Worker(s) Processing Responses : \$32.29
 - d) Cost to Process Each Response: \$8.07
 - e) Total Cost to Process Responses: \$4,972,660.00
- 3) Overall Labor Burden to the Federal Government
 - a) Total Number of Annual Responses: 4,616,000
 - b) Total Labor Burden: \$37,262,660.00

Part B: OPERATIONAL AND MAINTENANCE COSTS

- 1) Cost Categories
 - a) Equipment: \$0.00
 - b) Printing: \$450,000.00
 - c) Postage: \$0.00
 - d) Software Purchases: \$0.00
 - e) Licensing Costs: \$0.00
 - f) Other: \$0.00
- 2) Total Operational and Maintenance Cost: \$450,000.00

Part C: TOTAL COST TO THE FEDERAL GOVERNMENT

- 1) Total Labor Cost to the Federal Government: \$32,290,000.00
- 2) Total Operational and Maintenance Costs: \$450,000.00
- 3) Total Cost to the Federal Government: \$32,740,000.00
- 15. <u>Reasons for Change in Burden</u>

The burden has increased since the last approval due to the inclusion of the eligibility of children ages 5-11 years to receive the 2 dose COVID-19 vaccine.

16. <u>Publication of Results</u>

The results of this information collection will not be published.

17. <u>Non-Display of OMB Expiration Date</u>

We are not seeking approval to omit the display of the expiration date of the OMB approval on the collection instrument.

18. <u>Exceptions to "Certification for Paperwork Reduction Submissions"</u>

We are not requesting any exemptions to the provisions stated in 5 CFR 1320.9.