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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA-2018-0060]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections. This document describes the collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments identified by DOT Docket Number NHTSA-2018-0060 using any of the following methods:

Electronic submissions: Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M-30, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12-140, Washington, DC 20590.

Hand Delivery: West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Fax: 1-202-493-2251.

Instructions: Each submission must include the agency name and the docket number for this Notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION, CONTACT: Mary Byrd, Contracting Officer's Representative, Office of Behavioral Safety Research (NPD-320), National Highway Traffic Safety Administration, 1200 New Jersey Avenue, SE, Washington, DC 20590. Ms. Byrd's phone number is 202-366-5595, and her email address is mary.byrd@dot.gov.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the Federal Register providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (5 CFR 1320.8(d)), an agency must ask for public comment on the following:

i) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

iii) how to enhance the quality, utility, and clarity of the information to be collected; and

iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Emergency Medical Services Sleep Health and Fatigue Education

Type of Request: New information collection.

OMB Clearance Number: None.

Form Number: NHTSA Forms 1460, 1461, 1462, 1463, 1464, 1465, 1466, and 1467.

Requested Expiration Date of Approval: Three years from date of approval.

Summary of the Collection of Information: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from Emergency Medical Services (EMS) personnel who operate ambulances on the roadway for a one-time voluntary study to evaluate the effectiveness of a fatigue mitigation intervention that delivers education and training. Up to 200 EMS agencies across the United States will be contacted and screened in order to recruit a total of 30 agencies to participate in the study. NHTSA anticipates contacting up to 100 EMS personnel per participating agency (3,000 total) to screen and recruit 1,500 eligible participants for the study. NHTSA expects

1,200 voluntary participants to complete the sign-up process, including providing demographic information and shift schedules, and to consent to participate in the 24-week study. Participants will complete a baseline survey that includes self-reported fatigue and sleepiness and will retake the survey halfway through the study and again at the end of the study. All participants will complete the ten ten-minute training modules during the study period. Once the study is underway, participants will be asked to respond to daily text messages about sleepiness and fatigue for eight weeks of the 24-week study. Finally, NHTSA will ask 30 of the 1,200 participants to provide additional information by keeping a daily sleep diary for eight weeks and by taking a brief vigilance task test to measure fatigue at the beginning and end of each shift over eight days.

Background: The mission of the NHTSA is to save lives, prevent injuries and reduce economic costs due to motor vehicle crashes. In support of this mission, NHTSA's Office of Behavioral Safety Research studies behaviors and attitudes in highway safety, focusing on drivers, passengers, pedestrians, and motorcyclists, and it uses the results to develop and refine countermeasures to deter unsafe behaviors and promote safe alternatives. An efficient EMS system is integral to reducing injury and mortality on and off our Nation's highways and is key to ensuring prompt emergency response to any type of illness or injury. The Nation's best preparation for any incident, large or small, is a comprehensive EMS system, ready every day for every emergency.

A 2015 NHTSA study published at EMSworld.com found that on average there are 4,500 crashes per year involving ambulances, and these crashes result in an average of 33 deaths per year. As indicated in various media reports of high profile crashes, fatigue and sleep deprivation are likely contributors. Furthermore, a 2012 study by Patterson,

Weaver, Frank, et al. published in *Prehospital Emergency Care* found that the odds of injury, medical error, and safety-compromising behaviors among fatigued EMS personnel are twice that of personnel who do not report fatigue. A 2015 study by Patterson, Weaver and Hostler in *Emergency Medical Services: Clinical Practice and Systems Oversight* found that more than half of EMS personnel report fatigue, poor sleep, or inadequate recovery between shifts.

While greater than half of EMS personnel report work-related fatigue, there are no guidelines for the management of fatigue in EMS. In 2013, the National EMS Advisory Council (NEMSAC) adopted an advisory that recommended NHTSA and federal partners disseminate evidence-based information to aid the EMS community in efforts to develop fatigue risk management programs. In response, NHTSA kicked off the “Fatigue in EMS” initiative in 2016. The project aims to address the potential dangers of drowsiness and fatigue among EMS workers, including the risk of traffic crashes, injuries to providers and patients, and medical errors. After an extensive review of more than 30,000 published research articles, the project team released its evidence-based guidelines for fatigue risk management, along with companion materials and expert commentaries in January 2018. The guidelines, which are described in a 2018 publication by Patterson, Higgins, Van Dogen, et al. in *Prehospital Emergency Care*, intend to combat the effects of fatigue through the following five recommendations:

1. Reliable and/or valid fatigue and sleepiness survey instruments should be used to measure and monitor fatigue in EMS personnel.
2. EMS personnel should work shifts shorter than 24 hours in duration.
3. EMS workers should have access to caffeine as a fatigue countermeasure.

4. EMS personnel should have the opportunity to nap while on duty to mitigate fatigue.
5. EMS personnel should receive education and training to mitigate fatigue and fatigue-related risks.

Description of the Need for the Information and Proposed Use of the Information:

After developing and disseminating the evidence-based guidelines for fatigue risk management, the second phase of NHTSA's "Fatigue in EMS" initiative is to test the impact of one or more of the recommendations. NHTSA proposes to use the information collected to evaluate the effectiveness of the fifth recommendation, education and training, on reducing fatigue among EMS personnel. The overarching goals of this project are to determine whether providing education and training to EMS personnel on the importance of sleep health and dangers of fatigue affect diverse indicators of sleep, fatigue, and safety as well as to enhance our general understanding of the relationships between shift work, sleep, and fatigue in EMS operations. If the training is demonstrated to be effective at improving sleep quality and reducing fatigue, then it will be more widely distributed to the EMS community through State offices as well as through the National Association of State Emergency Medical Services Officials.

Data Collection Plan: Members of the research team will coordinate recruitment and enrollment of EMS organizations and individual EMS personnel. Recruitment will be limited to EMS organizations and affiliated personnel located in the United States. The research team will use webinars, conference calls, and a website to advertise the research study to those that may be interested. The team expects to collect information from as many as 200 organizations to recruit the target of 30 moderately-sized EMS organizations

(50 to 300 personnel) who provide around-the-clock ground-based services. The team will measure interest and eligibility using an agency-level screening form, which is estimated to take 5 minutes to complete for a total expected burden of 17 hours. The 30 participating agencies will then recruit EMS clinicians currently working full-time or part-time using a recruitment flyer distributed to employees. The research team expects to collect information from as many as 3,000 individuals to identify up to 1,500 eligible participants. The team will measure eligibility using an individual-level screening form, which is estimated to take 5 minutes to complete for a total expected burden of 250 hours.

The research team will have the 1,500 eligible individuals watch a video explaining the study and the consent process and will then ask them to indicate their consent to participate. The consenting process is expected to take 10 minutes for a total expected burden of 250 hours. The research team expects 1,200 eligible individuals to consent and agree to participate. These individuals will then complete the registration process including providing demographic information and shift schedules, complete a baseline survey including self-reported fatigue and sleepiness. Half of the participants will be asked to complete ten training sessions of ten minutes each within ten days. The other half will be asked to complete the training within ten days of the mid-point of the study. The expected burden for the registration process, baseline survey and training intervention is 145 minutes per participant for a total burden of 2,900 hours. Once the study is underway, participants will be asked to respond to daily text messages about sleepiness and fatigue for eight weeks of the 24-week study. The expected burden of responding is 5 minutes per response for a total burden of 5,600. The research team also

will ask participants to complete follow-up surveys at the study mid-point and at the end of the study. The expected burden of responding is 25 minutes per survey for a total burden of 1,000 hours.

A subset of participants (30 of the 1,200) will complete a daily sleep diary for eight weeks of the 24-week study. Completing the diary is expected to take 3 minutes per day for a total burden of 84 hours. This subset also will be asked to take a brief Psychomotor Vigilance Task test twice per day (at the start and at the end of shift) for a total of eight days spread across the study period. Completing each test is expected to take five minutes for a total burden of 40 hours. The purpose of these additional data collections is to assess the validity and reliability of the self-reported study measures.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information:

The total estimated burden for EMS agency recruitment (17 hours), recruitment of EMS clinicians (250 hours), the consenting process (250 hours), initial data collection and training (2,900), follow-up data collection (6,600), and additional data collection for assessing measurement error (124) is 10,141 hours.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, D.C. on July 12, 2018.

Jeff Michael,

Associate Administrator,

Research and Program Development.

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