

complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, 1200 New Jersey Ave. SE, W41-326, Washington DC 20590. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above. When you send a comment containing information claimed to be confidential business information, you should submit a cover letter setting forth the information specified in our confidential business information regulation (49 CFR part 512).

#### SUPPLEMENTARY INFORMATION:

##### Background

In the early 2000s, NHTSA convened a panel of international experts on drug-impaired driving to review developments in the field of drugs and human performance and to identify the specific effects that both high priority illicit and prescription drugs have on driving. The experts represented the fields of psychopharmacology, behavioral psychology, drug chemistry, forensic toxicology, medicine, and law enforcement. That effort resulted in the publication of a document entitled *Drugs and Human Performance Fact Sheets* (DOT HS 809 725) in June 2004.

Each Fact Sheet covered one of the selected sixteen drugs that impair driving. The selected drugs included over-the-counter medications such as dextromethorphan and diphenhydramine; prescription medications such as carisoprodol, diazepam, and zolpidem; and abused and/or illegal drugs such as cocaine, GHB, ketamine, LSD, marijuana, methadone, methamphetamine, MDMA, morphine, PCP, and toluene. Each individual drug Fact Sheet covered information regarding drug chemistry, usage and dosage information, pharmacology, drug effects, effects on driving, drug evaluation and classification, and the panel's assessment of driving risks. More specifically, the Fact Sheets provided details on the physical description of the drug, synonyms, and pharmaceutical or illicit sources; medical and recreational uses, recommended and abused doses, typical routes of administration, and potency and purity; mechanism of drug action and major receptor sites; drug absorption, distribution, metabolism and elimination data; blood and urine concentrations; psychological and physiological effects, and drug interactions; drug effects on

psychomotor performance effects; driving simulator and epidemiology studies; and drug recognition evaluation profiles. Each Fact Sheet concludes with general statements about the drugs' ability to impair driving performance. A list of key references and recommended reading was also provided for each drug.

Since 2004, new research on these and other impairing drugs has become available. As a result, NHTSA plans to evaluate whether additional drugs that impair driving should be included in the Fact Sheets and to add them as appropriate, as well as to update information on the effects of the sixteen aforementioned drugs on driving. NHTSA will base the revised Fact Sheets on the state of current scientific knowledge. The agency intends to design the revised Fact Sheets to continue to provide practical guidance to toxicologists, pharmacologists, law enforcement officers, attorneys, and the general public to use in the evaluation of future cases.

In order to assist on the development of the new edition of the Fact Sheets, NHTSA invites comments and suggestions from the general public on additional drugs as well as relevant research studies that have become available since 2004 that could be included in the updated fact sheets. To the extent possible, such comments and suggestions should be accompanied by information about the drug, including the extent of its use, its pharmacology and pharmacodynamics, and how impairing it is for driving, along with references.

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

Issued in Washington, DC, on July 12, 2018.

**Jeff Michael,**

*Associate Administrator, Research and Program Development.*

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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 September 17, 2018.

**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](mailto: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, DC, on July 12, 2018.

**Jeff Michael,**

*Associate Administrator, Research and Program Development.*

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## DEPARTMENT OF VETERANS AFFAIRS

### Health Services Research and Development Service, Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Health Services Research and Development Service Scientific Merit Review Board will conduct in-person and teleconference meetings of its eleven Health Services Research (HSR) subcommittees on the dates below from 8:00 a.m. to approximately 4:30 p.m. (unless otherwise listed) at the FHI 360 Conference Center, 1825 Connecticut Avenue NW, Washington, DC 20009 (unless otherwise listed):

- HSR 0—Community Care on August 21, 2018;
- HSR 1—Health Care and Clinical Management on August 21–22, 2018;
- HSR 2—Behavioral, Social, and Cultural Determinants of Health and Care on August 23–24, 2018;
- HSR 3—Healthcare Informatics on August 23, 2018;
- HSR 4—Mental and Behavioral Health on August 21–22, 2018;
- HSR 5—Health Care System Organization and Delivery on August 23–24, 2018;

- HSR 6—Post-acute and Long-term Care on August 22, 2018;
- HSR 7—Opioid and Pain Management Special Emphasis on August 24, 2018;
- MRA 0—Mentored Research on August 24, 2018;
- HSR 8—Implementation Research Project on August 23, 2018;
- HS8 A—Randomized Program Evaluations on August 23, 2018; and
- HSR 9—Learning Health Initiative on August 23, 2018.

The purpose of the Board is to review health services research and development applications involving: the measurement and evaluation of health care services; the testing of new methods of health care delivery and management; and mentored research. Applications are reviewed for scientific and technical merit, mission relevance, and the protection of human and animal subjects. Recommendations regarding funding are submitted to the Chief Research and Development Officer.

Each subcommittee meeting of the Board will be open to the public the first day for approximately one half-hour from 8:00 a.m. to 8:30 a.m. at the start of the meeting on August 21 (HSR 0, 1, 4), August 22 (HSR 1, 4, 6), August 23 (HSR 2, 3, 5, 8, 9, and HS8A), and August 24 (HSR 2, 5, 7, and MRA 0) to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the subcommittee meetings may dial 1 (800) 767-1750, participant code 10443#.

The remaining portion of each subcommittee meeting will be closed for the discussion, examination, reference to, and oral review of the intramural research proposals and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92-463, as amended by Public Law 94-409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).