

(EEI) Generic ICR (OMB Control Number 0920–1011, exp 1/31/2020). A full OMB package is being submitted to allow for continuation of the project.

Rocky Mountain spotted fever (RMSF), a life-threatening and rapidly progressive tickborne disease, is caused by infection with the bacterium *Rickettsia rickettsii*. Infection begins with non-specific symptoms like fever, headache, and muscle pain, but when left untreated the bacteria can cause damage to blood vessels throughout the body leading to organ and tissue damage. Delay in recognition and treatment of RMSF can result in irreparable damage leading to amputation of extremities, neurological

deficits (such as hearing loss, paralysis, and encephalopathy), and death.

Case series in the peer-reviewed literature document long term sequelae (LTS) from RMSF in anywhere from 3–55% of cases, yet characterization of the long-term impacts is still not well understood, and only a handful of studies have examined them in detail. Results of neurologic damage caused during acute RMSF illness may include symptoms ranging from paresthesia, insomnia and behavioral concerns to loss of hearing, motor or language dysfunction, and chronic pain.

This study will gather information related to neurologic sequela following RMSF illness. Information for this study will come from three sources: Medical

charts, patient interviews, and neurological exams with a cognitive/developmental assessment for children. Resulting data will provide information to healthcare providers, patients, and policy makers about the long term consequences of severe RMSF, including time to recovery, self-reported impact to daily function, and will look to identify risk factors during acute illness which may be associated with long term impairment.

There is no cost to respondents other than the time to participate. Total estimated burden is 126 hours. Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241).

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
General Public	Patient screening questionnaire	250	1	10/60	42
	Neurological exam form	125	1	40/60	84
Total					126

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–19–18AXG]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled *Maritime Illness Database and Reporting System (MIDRS)*. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on September 25, 2018 to obtain comments from the public and affected agencies. CDC did not receive public comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this

notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Maritime Illness Database and Reporting System (MIDRS)—NEW—National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this new information collection request (ICR) is to request a three-year Paperwork Reduction Act (PRA) clearance for CDC’s Maritime Illness Database and Reporting System (MIDRS). MIDRS is currently approved under *Foreign Quarantine Regulations (42 CFR part 71)* (OMB Control No. 0920–0134, Expiration Date: 05/31/2019), sponsored by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Operationally, CDC has divided the responsibilities for enforcing foreign quarantine regulations between the Vessel Sanitation Program (VSP) and the Division of Global Migration and Quarantine (DGMQ). VSP takes the lead on overseeing acute gastroenteritis (AGE) illness surveillance and outbreak investigation activities on passenger

ships, while DGMQ monitors all non-AGE illnesses and deaths on passenger vessels as well as all diseases of public health concern on all other conveyances with international itineraries bound for the United States. From 2012 to 2014 all ships submitted their AGE, non-AGE, and death reports to MIDRS using a common web portal; however program and reporting needs changed and dictated a need to move non-AGE illness and death reporting to a separate system. As of June 10, 2014, DGMQ has changed its routing method for receiving reports from ships. It no longer accepts non-AGE illness and death reports via MIDRS.

To complete the separation of shipboard quarantine and inspection functions across the two CDC national centers, the VSP seeks to transition all federally mandated AGE illness reporting activities to a new ICR housed within its own Center, since MIDRS is housed in and used exclusively by VSP.

DGMQ will continue to surveil non-AGE illnesses on cruise ships and all illnesses on other foreign to U.S. conveyances under *Foreign Quarantine Regulations (42 CFR part 71)* (OMB Control No. 0920-0134, expiration date 05/31/2019).

The MIDRS data collection system consists of a surveillance system that receives information electronically through a web-based reporting portal; data can also be submitted by phone, email or fax and entered into MIDRS by VSP. AGE cases reported to MIDRS are totals for the entire voyage and do not represent the number of active AGE cases at any given port of call or at disembarkation. The AGE log, 72-hour food/activity history and other required documentation are completed and maintained on the ship.

Data collected will allow VSP to quickly detect AGE outbreaks, provide epidemiologic and sanitation guidance to stop the outbreak, craft public health

recommendations to prevent future outbreaks, and monitor AGE illness trends to identify important changes over time.

There are two types of respondents for this data collection: Cruise ship medical staff or other designated personnel who report AGE cases, and AGE cases who provide information for the 72-hour food/activity histories. Of note, VSP will not receive any information from or about the AGE cases; this information is collected and owned by the cruise line and maintained on the ship as part of the AGE case's medical record. VSP reviews these records during operational inspections to confirm they are available if needed, and if there is an AGE outbreak or report of unusual AGE illness for a particular voyage.

CDC estimates the total annualized time burden is 1,537 hours. A summary of the estimated annualized burden hours is shown in the table below.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Cruise ship medical staff or other designated personnel.	71.21(c) Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS).	250	10	3/60
	71.21(c) Recordkeeping—Gastrointestinal Illnesses reports 24 and 4 hours before arrival (MIDRS).	250	1	1/60
	71.21(c) AGE Logs	250	10	10/60
	71.21 (c) Recordkeeping—medical records (AGE Logs).	250	1	1/60
	71.21(c) Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times.	250	3	5/60
	71.21(c) Recordkeeping—medical records (Interviews with AGE crew case cabin mates and immediate contacts to determine AGE illness status and documentation of interview dates/times).	250	1	1/60
	71.21(c) Documentation of 3-day pre-embarkation AGE illness assessment for all crew members.	250	5	3/60
	71.21(c) Recordkeeping—medical records (Documentation of 3-day pre-embarkation AGE illness assessment for all crew members).	250	1	1/60
	71.21(c) Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees.	250	1	3/60
	71.21(c) Recordkeeping—medical records (Documentation of date/time of last symptom and clearance to return to work for food and nonfood employees).	250	1	1/60
	71.21(c) Recordkeeping—medical records (72 hour food/activity histories).	250	1	1/60
	71.21(c) 72-hour food/activity history	5,000	1	10/60
	AGE passenger and crew cases			

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day-19-19GH; Docket No. CDC-2018-0116]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled "Evaluating the implementation and impact of a fall prevention program, including opioid medication management, in a hospital discharge setting." This study will evaluate the implementation and impact of a fall prevention program in a hospital discharge setting. Components of the program will target opioid medication management in the acute and post-acute settings, and referral to clinically effective programs to reduce the risk of falls and opioid misuse.

DATES: CDC must receive written comments on or before April 8, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0116 by any of the following methods:

- **Federal eRulemaking Portal:** *Regulations.gov*. Follow the instructions for submitting comments.
- **Mail:** Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal (*regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: *omb@cdc.gov*.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate 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;
2. Evaluate 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;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Evaluating the implementation and impact of a fall prevention program, including opioid medication management, in a hospital discharge setting—New—National Center for

Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Falls are the leading cause of injury, and injuries leading to death in older adults. Medications which affect the central nervous system can cause side effects that increase the chances of falling, such as dizziness, sedation, confusion, blurred vision, and orthostatic hypotension. Opioids are strongly associated with increased fall risk in older adults. When opioids are taken with other medications, like benzodiazepines, there can be a synergistic effect on cognition and physical function, potentially leading to a more pronounced injury or unintentional overdose.

A key intervention in the Centers for Disease Control and Prevention (CDC)'s fall prevention program STEADI (Stopping Elderly Accidents, Deaths, and Injuries) initiative is medication management to reduce the fall risk. Medication review and management, especially upon care transitions, can reduce inappropriate opioid use, the risk of injury, and improve patient health. This data collection will evaluate the implementation and impact of a fall prevention program, including opioid medication management, in a hospital discharge setting. Components of the program will target opioid medication management in the acute and post-acute settings and referral to clinically effective programs to reduce the risk of falls and opioid misuse. This data collected will be used to: (1) Examine post-discharge use of opioids or alternative therapies for pain management among older adult patients, (2) examine post-discharge compliance and follow up by older adults with primary care doctors and/or specialist referrals for pain management and fall prevention efforts, (3) identify rate of readmission for a fall by level of patient compliance and follow-up post-discharge, (4) evaluate the uptake of the program by clinical staff, and (5) identify opportunities for program and process improvement.

The study population will be limited to older adults (65 years and older) considered high risk due to opioid use identified during discharge at a specific Medical Center inpatient. The study population for the clinical staff evaluation questionnaire will be limited to the same Medical Center clinical staff (i.e., nurses, pharmacists, physicians) involved in older-adult patient pain management and post-discharge planning that work in hospital units where this program has been