

e.g., permitting electronic submissions of responses.

- 5. Assess information collection costs.

**Proposed Project**

The Maternal Mortality Review Information Application (MMRIA) –New–National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The Centers for Disease Control and Prevention (CDC) seeks OMB approval to collect information through the Maternal Mortality Review Information Application (MMRIA) for three years. MMRIA is a standardized data collection system that allows Maternal Mortality Review Committees (MMRCs) across the country to abstract relevant data (clinical and non-clinical) from a variety of sources, document committee decisions, and analyze data in order to better understand the contributing factors and preventability of maternal deaths and thus to develop recommendations for prevention.

About 700 women die each year in the United States as a result of pregnancy or delivery complications, a chain of events initiated by pregnancy, or the aggravation of an unrelated condition by the physiologic effects of pregnancy. Furthermore, considerable racial disparities exist, with black women almost four times more likely to die from pregnancy-related complications than white women. Findings from MMRCs indicate that

more than half of maternal deaths are preventable.

Maternal Mortality Review is a process by which a multidisciplinary committee at the jurisdiction level identifies and reviews cases of maternal death within one year of end of pregnancy. Members of MMRCs typically represent public health, obstetrics and gynecology, maternal-fetal medicine, nursing, midwifery, forensic pathology, mental and behavioral health, and other relevant stakeholders. Through a partnership among the MMRC, state vital records office, and epidemiologists, deaths among women of reproductive age are examined to determine if they occurred during pregnancy or within one year of the end of pregnancy (i.e., pregnancy-associated deaths). Through this process, potential cases of pregnancy-related deaths (i.e., maternal death from any cause related to or aggravated by pregnancy or its management) are then identified. Review committees access multiple sources of clinical and non-clinical information to understand the circumstances surrounding a maternal death in order to develop recommendations for action to prevent similar deaths in the future.

MMRIA is a standardized data collection system designed to collect timely, accurate, and standardized information about deaths to women during pregnancy and within one year of end of pregnancy, including opportunities for prevention, within and across jurisdictions. Data will be abstracted and entered into MMRIA

from various sources, including death certificates, autopsy reports, birth certificates, prenatal care records, emergency room visit records, hospitalization records, records from other medical office visits, medical transport records, social and environmental profiles, mental health profiles, and informant interviews. Case narratives for committee reviews are auto-populated from the abstracted data entered into MMRIA to facilitate committee review, and committee decisions will also be entered into MMRIA.

The data collected in MMRIA will be used to facilitate an understanding of the drives of maternal mortality and complications of pregnancy and associated disparities; determine what interventions at patient, provider, facility, system, and community levels will have the most impact; and implement data driven recommendations.

The burden estimates presented here are applicable to the estimated 25 awardees of the cooperative agreement *Preventing Maternal Deaths: Supporting Maternal Mortality Review Committees* (CDC–RFA–DP19–1908); these awardees are required to compile a defined set of information about maternal deaths into MMRIA. It is estimated that information will be collected for a total of 740 pregnancy-associated deaths on average, annually, among the 25 awardees. Burden is estimated based on each awardee’s total staff time to enter the abstracted data into MMRIA and enter the committee decision.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Types of respondents	Form name	Number of respondents	Number of responses per respondent	Average hours per response (in hours)	Total burden hours
Awardees .....	Data abstraction .....	25	30	15	11,250
	Committee decision .....	25	30	24/60	300
Total .....	.....	.....	.....	.....	11,550

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30Day–19–1108]**

**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 *Paul Coverdell*

*National Acute Stroke Program (PCNASP)* to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on February 7, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments 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](mailto: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

Paul Coverdell National Acute Stroke Program (PCNASP) (OMB No. 0920-1108, exp. 03/31/2019)—Reinstatement with Change—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

### Background and Brief Description

Stroke is the fifth leading cause of death in the United States and results in approximately 145,000 deaths per year. Additionally, approximately 800,000 stroke events are reported each year, including approximately 185,000 recurrent strokes. However, many strokes are preventable, and patient outcomes can be improved through coordinated care that begins at stroke onset and is delivered in a timely manner.

Stroke outcomes depend upon the rapid recognition of signs and

symptoms of stroke, prompt transport to a treatment facility, and early rehabilitation. Improving outcomes requires a coordinated systems approach involving pre-hospital care, emergency department and hospital care, prevention of complications, post-stroke rehabilitation, and ongoing secondary prevention. Through the Paul Coverdell National Acute Stroke Program (PCNASP), CDC has been continuously working to measure and improve acute stroke care using well-known quality improvement strategies coupled with frequent evaluation of results. PCNASP awardees are state health departments who work with participating hospitals, Emergency Medical Services (EMS) agencies, and other healthcare partners (*e.g.*, post-stroke recovery facilities) in their jurisdictions to improve quality of care and transitions of care for stroke patients. During initial cooperative agreement cycles, PCNASP awardees focused on improving in-hospital quality of care (QoC) with technical assistance provided by CDC. Through lessons learned during this process and other supporting evidence in the field, it has become evident that it is also important to examine pre- and post-hospital transitions of care to link the entire continuum of stroke care when improving QoC for stroke patients.

The PCNASP's current five-year cooperative agreement started on July 1, 2015 and includes nine awardees and their selected partners (hospitals, EMS agencies, other healthcare facilities). This current funding reflects additional emphasis on pre-hospital quality of care as well as the post-hospital transition of care setting from hospital to home or other healthcare facility. With technical assistance provided by CDC, awardees have worked on identifying and using data systems to systematically collect and report data on all three phases of the stroke care continuum and on hospital capacity.

PCNASP had OMB approval for the collection of pre-hospital (EMS), in-hospital, and post-hospital patient care data, as well as hospital inventory data (OMB No. 0920-1108). This approval expired on 3/31/2019, and awardees have discontinued data submission. The lapsed information collection will resume after OMB approval of a reinstatement package.

When possible, in-hospital patient care data continues to align with standards set by The Joint Commission (TJC) and the American Heart

Association's Get With The Guidelines (GWTG) program. There are no changes to the estimated burden for the collection of in-hospital data. The average burden per response remains 30 minutes for awardees, for a total of 18 hours annually.

Data collection methods for pre- and post-hospital care data are revised to allow for information collection through existing data systems, including GWTG and the National Emergency Medical Services Information System (NEMSIS). CDC has worked with awardees, the American Heart Association and NEMSIS to identify areas of alignment and new collaboration to reduce the burden of pre-hospital data collection. The average burden per response will vary from 30 minutes to two hours. Thus, the burden for pre-hospital data is being reduced from 96 to 60 burden hours annually. Similarly, the burden for post-hospital data is reduced from 38 to 22 burden hours annually, because data collection will occur using GWTG or another similar mechanism, and data will be transmitted automatically to awardees. The average burden per response will vary from 30 minutes to two hours per quarter for post-hospital data collection.

Primary data collection of hospital inventory data is collected to understand the capacity and infrastructure of the hospitals that admit and treat stroke patients. The average burden per response remains 30 minutes for hospitals, and eight hours for each PCNASP awardee to prepare an aggregate hospital inventory file. The number of respondents is increasing from 315 to 378 hospital partners due to increased participation in PCNASP. Thus, the burden for hospital inventory data is increasing from 230 to 261 hours annually.

These requested changes will result in a net decrease in total average burden from 382 to 361 hours. All patient, hospital, and EMS provider data that is submitted to CDC by PCNASP awardees will be de-identified and transmitted through secure data systems. Proposed data elements and quality indicators may be updated over time to include new or revised items based on evolving recommendations and standards in the field to improve the quality of stroke care.

OMB approval is requested for three years. Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
PCNASP Awardee .....	Hospital inventory .....	9	1	8
	In-hospital care data .....	9	4	30/60
	Pre-hospital care data .....	2	4	30/60
	7	4	2	
	Post-hospital transition of care data .....	7	4	30/60
PCNASP Hospital Partners .....	2	4	1	
	Hospital Inventory .....	378	1	30/60

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2019-N-1482]

**Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Extension of Comment Period**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** of April 3, 2019. The notice announced a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. In addition, it notified the public that FDA was establishing a docket for public comment on this hearing and that the docket would close on July 2, 2019. We are extending the comment period to give interested parties more time to comment.

**DATES:** FDA is extending the comment period on the notice published in the **Federal Register** of April 3, 2019 (84 FR 12969). Submit either electronic or written comments by July 16, 2019.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2019. The <https://www.regulations.gov> electronic filing system will accept

comments until 11:59 p.m. Eastern Time at the end of July 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2019-N-1482 for “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the