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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-20-20DC; Docket No. CDC-2019-0113]

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 “2019 Lung Injury Response Understanding Vaping Practices In the United States.” This is a formative study to identify why people are getting sick after vaping/dabbing, in order to narrow the list of products, substances, and risk factors requiring further public health action.

DATES: CDC must receive written comments on or before February 21, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0113 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 Jeffrey M. Zirger, 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

2019 Lung Injury Response Understanding Vaping Practices In the United States—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center for Injury Prevention and Control (NCIPC)

requests approval for a New Information Collection, “2019 Lung Injury Response Understanding Vaping Practices In the United States.”

In early August 2019, initial cases of e-cigarette, or vaping, product use associated lung injury (EVALI) were reported to CDC. As of November 13, 2019, 2,172 EVALI cases have been reported to CDC from 49 states, the District of Columbia, the US Virgin Islands, and Puerto Rico; 42 deaths have been reported among these cases. A multi-state centrally coordinated response for this severe pulmonary injury was established at CDC to assist each state/local/territory jurisdiction in making rapid, practical decisions for actions to prevent and control this public health problem.

To date, all EVALI patients have reported a history of using e-cigarette, or vaping, products. The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak. In addition, vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). However, while it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak. At present, there is very little data on which to compare EVALI cases to individuals who are vaping the same products at the same frequency but have not developed EVALI. Comparing EVALI cases to people who vape but have not developed EVALI in a timely way is very important for narrowing the list of products, substances, and risk factors requiring further public health action (e.g., continuing to refine communication messages) and additional studies (e.g., prioritizing samples for laboratory testing). Further, there is insufficient data for guiding the selection of controls for a rigorous case control study (lack of uniformity in demographic characteristics and product brands and types).

The data collected will be used to identify product types, “brands”, devices, and frequency of use (collectively referred to as use characteristics) from a geographically diverse convenience sample of individuals who report vaping THC but have not developed EVALI. These data will enable CDC to compare the

frequency of use characteristics between the convenience sample and EVALI cases to prioritize follow up on hypotheses about potential risk factors and causes of the outbreak as well as to refine, target, and prioritize additional information gathering, *e.g.*, epidemiological analyses, laboratory testing, and analysis of pathological specimen.

The proposed approach leverages on an opt-in internet panel survey to rapidly collect specific information on a

demographically and geographically diverse convenience sample of individuals who report vaping THC but have not developed EVALI. Because such sampling frame is not population representative and not suitable for generalizing about populations, only unweighted data will be obtained from the opt-in internet panel survey and only unweighted, aggregate results will be shared with partners or publicly. The data collected will not be used to produce national, regional, or state-

representative estimates; rather, the data will be used to help prioritize hypotheses for future epidemiological, laboratory, and clinical analyses as part of CDC's ongoing lung injury response.

There is no cost to respondents other than the time to participate. The annualized burden is estimated at 5,000 hours. Authorizing legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241).

ESTIMATED TOTAL BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Individuals	Understanding Vaping Practices in the United States Survey—screening questions.	120,000	1	2/60	4,000
Individuals	Understanding Vaping Practices in the United States Survey—full survey.	6,000	1	10/60	1,000
Total	5,000

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[30Day-20-19BDE]

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 “The Maternal Mortality Review Information Application (MMRIA)” 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 June 20, 2019 to obtain comments from the public and affected agencies. CDC received four 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*. 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

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.