

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)
Middle and High School Age Adolescents.	Youth Questionnaire	20,000	1	50/60	16,667
Middle and High School Age Adolescents.	Pre/Post youth questionnaire	10,000	2	50/60	16,667
Middle and High School Age Adolescents.	Youth interview/focus group guide ...	3,000	2	1.5	9,000
Parents/caregivers of adolescents	Parent/Caregiver questionnaire	7,500	2	25/60	6,250
Parents/caregivers of adolescents	Parent/Caregiver interview/focus group guide.	3,000	2	1.5	9,000
Total	57,584

Jeffery 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-19-0978; Docket No. CDC-2018-0098]

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 Emerging Infections Program (EIP). The EIP is a population-based surveillance activity performed via active, laboratory case finding that is used for detecting, identifying, and monitoring emerging pathogens.

DATES: CDC must receive written comments on or before January 14, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0098 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

Emerging Infections Program OMB# 0920-0978 Exp. Date: 05/31/2021—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Emerging Infections Programs (EIPs) are population-based centers of excellence established through a network of state health departments collaborating with academic institutions; local health departments; public health and clinical laboratories; infection control professionals; and healthcare providers. EIPs assist in local, state, and national efforts to prevent, control, and monitor the public health impact of infectious diseases.

Activities of the EIPs fall into the following general categories: (1) Active surveillance; (2) applied public health epidemiologic and laboratory activities; (3) implementation and evaluation of

pilot prevention/intervention projects; and (4) flexible response to public health emergencies. Activities of the EIPs are designed to: (1) Address issues that the EIP network is particularly suited to investigate; (2) maintain sufficient flexibility for emergency response and new problems as they arise; (3) develop and evaluate public health interventions to inform public

health policy and treatment guidelines; (4) incorporate training as a key function; and (5) prioritize projects that lead directly to the prevention of disease.

A revision is being submitted to make existing collection instruments clearer and to add several new forms specifically surveying laboratory practices. These forms will allow the

EIP to better detect, identify, track changes in laboratory testing methodology, gather information about laboratory utilization in the EIP catchment area to ensure that all cases are being captured, and survey EIP staff to evaluate program quality.

The total estimated burden is 40,601 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
State Health Department	ABCs Case Report Form	10	809	20/60	2697
	ABCs Invasive Pneumococcal Disease in Children Case Report Form.	10	22	10/60	37
	ABCs <i>H.influenzae</i> Neonatal Sepsis Expanded Surveillance Form.	10	6	10/60	10
	ABCs Severe GAS Infection Supplemental Form	10	136	20/60	453
	ABCs Neonatal Infection Expanded Tracking Form.	10	37	20/60	123
	FoodNet Campylobacter	10	942	21/60	3297
	FoodNet Cyclospora	10	163	10/60	272
	FoodNet Listeria monocytogenes	10	15	20/60	50
	FoodNet Salmonella	10	789	21/60	2761
	FoodNet Shiga toxin producing E. coli	10	205	20/60	683
	FoodNet Shigella	10	213	10/60	355
	FoodNet Vibrio	10	34	10/60	56
	FoodNet Yersinia	10	48	10/60	80
	FoodNet Hemolytic Uremic Syndrome Case Report Form.	10	10	1	100
	FoodNet Clinical Laboratory Practices and Testing Volume—NEW.	10	70	20/60	233
	Influenza Hospitalization Surveillance Network Case Report Form.	10	1000	25/60	4167
	Influenza Hospitalization Surveillance Project Vaccination Phone Script Consent Form (English/Spanish).	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Vaccination Phone Script (English/Spanish).	10	333	5/60	278
	Influenza Hospitalization Surveillance Project Provider Vaccination History Fax Form (Children/Adults).	10	333	5/60	278
	FluSurv-NET Laboratory Survey—NEW	10	23	10/60	38
	HAIC CDI Case Report Form	10	1650	35/60	9625
	HAIC CDI Annual Laboratory Survey—NEW	10	16	10/60	27
	HAIC CDI Annual Surveillance Officers Survey—NEW.	10	1	15/60	3
	HAIC CDI LTCF Survey—NEW	10	45	5/60	38
	HAIC Multi-site Gram-Negative Bacilli Case Report Form (<i>MuGSI-CRE/CRAB</i>).	10	500	25/60	2083
	HAIC Multi-site Gram-Negative Surveillance Initiative—Extended-Spectrum Beta-Lactamase-Producing Enterobacteriaceae (<i>MuGSI-ESBL</i>).	10	1200	25/60	5000
	HAIC Invasive Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA).	10	474	25/60	1975
	HAIC Invasive Methicillin-sensitive <i>Staphylococcus aureus</i> (MSSA).	10	754	25/60	3142
	HAIC Invasive <i>Staphylococcus aureus</i> Annual Laboratory Survey—NEW.	10	11	8/60	15
	HAIC Invasive <i>Staphylococcus aureus</i> Annual Surveillance Officers Survey—NEW.	10	1	10/60	2
HAIC Candidemia Case Report Form	9	800	20/60	2400	
HAIC Candidemia Periodic Laboratory Survey—NEW.	9	15	20/60	45	
Total	40,601

Jeffrey M. Zirger,

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

[FR Doc. 2018-24969 Filed 11-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10688]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 14, 2019.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following

address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10688 Home Health (HH) National Provider Survey

Under the 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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

Type of Information Collection Request: New collection (Request for a new OMB control number); *Title of Information Collection:* Home Health (HH) National Provider Survey; *Use:* Section 1890A(a)(6) of the Social

Security Act (the Act) requires the Secretary of HHS every three years to assess the quality and efficiency effects of the use of endorsed measures in specific Medicare quality reporting and incentive programs. This request is for review and approval of a survey and qualitative interview guide for the home health setting, which CMS proposes to use to address critical needs regarding the impact of use of quality and efficiency measures in the home health setting, including the burden they impose on home health agencies.

CMS plans to use the findings from surveys and qualitative interviews for multiple purposes. The qualitative interviews and standardized survey will inform CMS about the impact of measures used to assess care in HHAs. The surveys will help CMS understand whether the use of performance measures has been associated with changes in HHA behavior—namely, what quality improvements (QI) investments HHAs are making and whether adoption of QI changes is associated with higher performance on the measures. The survey will help CMS identify characteristics associated with high performance, which, if understood, could be used to leverage improvements in care among lower-performing HHAs. The survey and interviews, assuming approval by August 2019, would be fielded from fall 2019 through spring 2020. *Form Number:* CMS-10688 (OMB control number: 0938-NEW); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 1,040; *Total Annual Responses:* 1,040; *Total Annual Hours:* 1,040. (For policy questions regarding this collection contact Noni Bodkin at 410-786-7837.)

Dated: November 9, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-24951 Filed 11-14-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3692]

Evaluating the Pressor Effects of Drugs; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.