

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

Who's at Risk: From Hazards to Communities—An Approach for Operationalizing CDC Guidelines to Determine Risks, and Define, Locate, and Reach At-Risk Populations in Public Health Emergencies—New—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Risk Assessment, Mapping, and Planning (RAMP) tool is currently being developed by CDC for public health and medical emergency planners (especially Public Health Emergency Preparedness and Hospital Preparedness Program awardees) to assess and quantify risk, identify and map at-risk populations, and to determine response objectives for hazard-specific public health emergency plans at all jurisdictional levels in the United States.

To assist in developing this tool, CDC will conduct key informant interviews/ focus groups with public health and emergency management professionals from across the United States. To understand the needs of at-risk populations, CDC will also administer an anonymous survey to respondents from Los Angeles County Department of Public Health clinics.

CDC seeks to obtain subject matter expertise and feedback for pilot testing the RAMP tool and anonymous demographic information from LA County DPH clinic guests. CDC will use the data to develop the RAMP tool.

Public health and emergency manager respondents in pre-identified partner

jurisdictions will participate in the interview and focus groups.

CDC will offer Los Angeles Department of Public Health Clinic guests the Community Emergency Preparedness Survey in order to determine community perspectives on several emergency preparedness and response topics. CDC will offer the Community Emergency Preparedness Survey anonymously to three separate types of community members: LA County Public Health Center Clients, LA County Community Partner Stakeholders, and LA County Community Residents.

CDC will collect information with the use of paper surveys. CDC will enter the information from the paper survey into a secured database. CDC will lock all paper surveys in the secure offices of the Los Angeles County Department of Public Health Emergency Preparedness and Response Division. CDC will disseminate and report results in aggregate form only. The total number of estimated annual burden hours is 226. There are no costs to the 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)
Public Health and Medical Emergency Planners.	Focus Group Questionnaire	100	1	1
LA County Public Health Center Guests	Community Emergency Preparedness Survey.	500	1	5/60
LA County Community Partner Stakeholders	Community Emergency Preparedness Survey.	500	1	5/60
LA County Community Residents	Community Emergency Preparedness Survey.	500	1	5/60

Leroy A. Richardson,
 Chief, Information Collection Review Office,
 Office of Scientific Integrity, Office of the
 Associate Director for Science, Office of the
 Director, Centers for Disease Control and
 Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10653]

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 8, 2018.

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’ Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

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–10653 Coverage of Certain Preventive Services Under the Affordable Care Act

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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Coverage of Certain Preventive Services Under the Affordable Care Act; *Use:* The 2017 interim final regulations titled “Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” and “Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act” expand exemptions for religious beliefs and moral convictions for certain entities or individuals whose health plans may otherwise be subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. The interim final rules extend the exemption to health insurance issuers that hold religious or moral objections in certain circumstances. The interim final rules also allow plan participants and enrollees with sincerely held religious or moral objections to request coverage that does not include contraceptive services.

The interim final rules also leave the accommodation process in place as an optional process for objecting entities who wish to use it voluntarily. To avoid contracting, arranging, paying, or referring for contraceptive coverage, an organization seeking to be treated as an eligible organization may self-certify (by using EBSA Form 700), prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization. The eligible organization must provide a copy of its self-certification to each health insurance issuer that would otherwise provide such coverage in connection with the health plan (for insured group health plans or student health insurance coverage). The issuer that receives the self-certification must provide separate payments for contraceptive services for plan participants and beneficiaries (or students and dependents). For a self-insured group health plan, the self-certification must be provided to its third party administrator. An eligible organization may alternatively submit a

notification to HHS as an alternative to submitting the EBSA Form 700 to the eligible organization’s health insurance issuer or third party administrator. A health insurance issuer or third party administrator providing or arranging payments for contraceptive services for participants and beneficiaries in plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations must provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

Eligible organizations can revoke at any time the accommodation process if participants and beneficiaries receive written notice of such revocation from the issuer or third party administrator in accordance with guidance issued by the Secretary, and if the accommodation process is currently being utilized, such revocation will be effective on the first day of the first plan year that begins on or after thirty days after the date of revocation. *Form Number:* CMS–10653 (OMB control number 0938–1344); *Frequency:* On Occasion; *Affected Public:* Private Sector; *Number of Respondents:* 110; *Number of Responses:* 274,629; *Total Annual Hours:* 181. (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650. For all other issues call (410) 786–1326.)

Dated: November 3, 2017.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1504]

Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled “Recurrent Herpes Labialis: Developing Drugs for Treatment and Prevention.” The purpose of this guidance is to assist sponsors in all phases of development of treatments for recurrent herpes