

Quality Promotion (DHQP), the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), the Director, CDC, the Secretary, Health and Human Services regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Considered: The agenda will include updates from the following HICPAC workgroups: The Healthcare Personnel Guideline Workgroup and the Neonatal Intensive Care Unit (NICU) Guideline Workgroup. Agenda items are subject to change as priorities dictate.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019-14067 Filed 7-1-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Public Comment Request; Performance Data for the Senior Medicare Patrol (SMP) Program; OMB# 0985-0024

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This Extension without Change (ICR Ext) solicits comments on the information collection requirements

related to the Performance Data for the Senior Medicare Patrol (SMP) Program.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by September 3, 2019.

ADDRESSES: Submit electronic comments on the collection of information to: Phillip McKoy, *Phillip.McKoy@acl.hhs.gov*. Submit written comments on the collection of information to Administration for Community Living, Washington, D.C. 20201, Attention: Phillip McKoy

FOR FURTHER INFORMATION CONTACT: Phillip McKoy, Office of Healthcare Information and Counseling (OHIC), Administration for Community Living, Washington, DC 20201, Phone: 202-795-7397, Email: *Phillip.Mckoy@acl.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined as and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The purpose of this data collection is to collect annual performance data from

grantees. This data collection is required by Congress for program monitoring and Government Performance Results Act (GPRA) purposes. The data collected through this request is used by ACL and the SMP Programs to communicate with Congress and the public on SMP activities. There are 54 programs nationally, one in all 50 states, the District of Columbia, Puerto Rico, Guam and the U.S. Virgin Islands. It is imperative that data be collected to ensure that grantees' contacts are captured and that Medicare beneficiaries are given the tools to prevent, detect and report health care fraud, error and abuse. The respondents for this data collection are grantees, SMP team members, and volunteers who meet with Medicare beneficiaries in group settings and in one-on-one sessions to educate them on the importance of being aware of Medicare fraud, error and abuse, and having the knowledge to protect the Medicare system.

Under Public Law 104-208, the Omnibus Consolidated Appropriations Act of 1997, Congress established the Senior Medicare Patrol Projects in order to further curb losses to the Medicare program. The Senate Committee noted that retired professionals, with appropriate training, could serve as educators and resources to assist Medicare beneficiaries and others to detect and report error, fraud and abuse.

Among other requirements, it directed the Administration for Community Living to work with the Office of Inspector General (OIG) and the Government Accountability Office (GAO), to assess the performance of the program. The Administration for Community Living has worked with HHS/OIG to develop project-level performance measures. The HHS/OIG has collected SMP performance data and issued SMP performance reports since 1997. The OIG changed the reporting period from twice a year to once a year in 2008.

This information is used by ACL as the primary method for monitoring the SMP Projects. This information collection reports the number of active team members, number of community outreach activities, number of beneficiaries reached by education and outreach activities, and the number of dollars recoverable for the Medicare Trust Fund among other performance measures. The information from the current collection is reported by the OIG to Congress and the public.

Measures as required by Congress and the Government Performance Results Modernization Act of 2010 (GPRMA), are also supported in ACL tracking

performance outcomes and efficiency measures with respect to the annual and long-term performance targets established in compliance with the GPRAMA. The Performance Data for the SMP data collection will continue to provide data necessary to determine the effectiveness of the program.

The proposed data collection tools may be found on the ACL website for review at <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden

ACL estimates the burden associated with this collection of information as

follows: The burden hours are based on the number of projects for 54 SMP grantees. With an estimated time of 138 burden hours per response for a total of 7,452 annual burden hours.

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
SMP grantees	SMP Project annual Report Form	54	1	138	7,452

Dated: June 26, 2019.
Mary Lazare,
Principal Deputy Administrator.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-1917]

Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products—Content and Format; Draft 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 draft guidance for industry entitled “Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.” This guidance is intended to assist applicants in writing the DRUG ABUSE AND DEPENDENCE section of the labeling, as described in the regulations for the content and format of labeling for human prescription drug and biological products. The recommendations in this draft guidance will help ensure that the labeling is clear, concise, useful and informative, and, to the extent possible, consistent in content and format within and across drug and therapeutic classes.

DATES: Submit either electronic or written comments on the draft guidance by September 3, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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-D-1917 for “Drug Abuse and Dependence Section of Labeling for Human Prescription Drug and Biological

Products—Content and Format.”

Received comments 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.” The Agency will review this copy, including the claimed confidential information, in its 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 <http://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 electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the