Background and Brief Description

The National Center for Health Statistics (NCHS) has submitted a six-month OMB emergency clearance for a Research and Development Survey (RANDS) COVID–19 related data collection. Since COVID–19 has resulted in a public health crisis, this information collection requests approval to conduct a follow-on survey (Round 3) to the previously completed rounds of RANDS. Similar to the previous two rounds of RANDS completed during COVID–19, this information collection will use NORC’s AmeriSpeak Panel as its sample source.

The RANDS COVID–19 (Round 3) collection will be used for the purpose of continuing NCHS’ developmental survey methods and will generate data that can help explain health-related experiences of the United States population during this period. The data collection includes not only a research component, but will also contribute to CDC’s ongoing surveillance of the COVID–19 pandemic. Given the current outbreak and the resulting limitations placed on NCHS’ other data collections, RANDS will provide NCHS and CDC with early estimates of COVID–19-related concepts. The questionnaire will cover areas such as general health, psychological distress, chronic conditions, health behaviors, the outbreak’s effects on healthcare access, loss of work due to illness with COVID–19, telemedicine access and use, and other health and behavioral aspects related to the epidemic. CDC requests approval for an estimated 1,734 burden hours over the course of the six-month approval. There are no costs to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN TABLE**

<table>
<thead>
<tr>
<th>Types of respondents</th>
<th>Form name</th>
<th>Number of participants</th>
<th>Number of responses/participant</th>
<th>Average hours per response</th>
<th>Response burden (in hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals or households</td>
<td>RANDS–COVID–19 Round 3</td>
<td>5,200</td>
<td>1</td>
<td>20/60</td>
<td>1,734</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


[FR Doc. 2021–02950 Filed 2–11–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention


**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 “NCHHSTP Generic Clearance Formative Research and Tool Development”. This information collection request is designed to allow CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) to conduct formative research information collection activities used to inform many aspects of surveillance, communications, health promotion, and research project development for NCHHSTP’s four priority diseases (HIV/AIDS), sexually transmitted diseases/infections (STD/STI), viral hepatitis, tuberculosis elimination (TB), and school and adolescent health (DASH).

DATES: CDC must receive written comments on or before April 13, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0010 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: 404–639–7118; 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.
understand the interests, attributes and needs of different populations and persons in that community. Formative research is research that occurs before a program is designed and implemented, or while a program is being conducted. NCHHSTP formative research is necessary for developing new programs or adapting programs that deal with the complexity of behaviors, social context, cultural identities, and health care that underlie the epidemiology of HIV/AIDS, viral hepatitis, STDs, and TB in the U.S., as well as for school and adolescent health.

CDC conducts formative research to develop public-sensitive communication messages and user friendly tools prior to developing or recommending interventions, or care. Sometimes these studies are entirely behavioral but most often they are cycles of interviews and focus groups designed to inform the development of a product. Products from these formative research studies will be used for prevention of HIV/AIDS, Sexually Transmitted Infections (STI), viral Hepatitis, and Tuberculosis. Findings from these studies may also be presented as evidence to disease-specific National Advisory Committees, to support revisions to recommended prevention and intervention methods, as well as new recommendations.

Much of CDC’s health communication takes place within campaigns that have lengthy planning periods—timeframes that accommodate the standard Federal process for approving data collections. Short term qualitative interviewing and cognitive research techniques have previously proven invaluable in the development of scientifically valid and population-appropriate methods, interventions, and instruments.

This request includes studies investigating the utility and acceptability of proposed sampling and recruitment methods, intervention contents and delivery, questionnaire domains, individual questions, and interactions with project staff or electronic data collection equipment. These activities will also provide information about how respondents answer questions and ways in which question response bias and error can be reduced.

This request also includes collection of information from public health programs to assess needs related to initiation of a new program activity or expansion or changes in scope or implementation of existing program activities to adapt them to current needs. The information collected will be used to advise programs and provide capacity-building assistance tailored to identified needs. Overall, these development activities are intended to provide information that will increase the success of the surveillance or research projects through increasing response rates and decreasing response error, thereby decreasing future data collection burden to the public. The studies that will be covered under this request will include one or more of the following investigational modalities: (1) Structured and qualitative interviewing for surveillance, research, interventions and material development, (2) cognitive interviewing for development of specific data collection instruments, (3) methodological research (4) Usability testing of technology-based instruments and materials, (5) field testing of new methodologies and materials, (6) investigation of mental models for health decision-making, to inform health communication messages, and (7) organizational needs assessments to support development of capacity.

Respondents who will participate in individual and group interviews (qualitative, cognitive, and computer assisted development activities) are selected purposively from those who respond to recruitment advertisements. In addition to utilizing advertisements for recruitment, respondents who will participate in research on survey methods may be selected purposively or systematically from within an ongoing surveillance or research project. Participation by respondents is voluntary. There is no cost to participants other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

<table>
<thead>
<tr>
<th>Type of respondent</th>
<th>Form name</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average hours per response</th>
<th>Total response burden (hours)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General public and health care providers.</td>
<td>Screener</td>
<td>81,200</td>
<td>1</td>
<td>10/60</td>
<td>13,533</td>
</tr>
<tr>
<td>General public and health care providers.</td>
<td>Consent Forms</td>
<td>40,600</td>
<td>1</td>
<td>5/60</td>
<td>3,383</td>
</tr>
<tr>
<td>General public and health care providers.</td>
<td>Individual Interview</td>
<td>6,600</td>
<td>1</td>
<td>1</td>
<td>6,600</td>
</tr>
<tr>
<td>General public and health care providers.</td>
<td>Focus Group Interview</td>
<td>4,000</td>
<td>1</td>
<td>2</td>
<td>8,000</td>
</tr>
</tbody>
</table>
Jeffrey M. Zirger,
Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.
[FR Doc. 2021–02952 Filed 2–11–21; 8:45 am]
BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

Centers for Medicare & Medicaid
Services
[Document Identifiers CMS–10518 and
CMS–10340]

Agency Information Collection
Activities: Proposed Collection;
Comment Request
AGENCY: Centers for Medicare &
Medicaid Services, Health and Human
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
April 13, 2021.
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
https://www.cms.gov/Regulations-and-
Guidance/Legislation/
PaperworkReductionActof1995/PRA-
Listing.html.
FOR FURTHER INFORMATION CONTACT:
William N. 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–10518 Application for Participation
in the Intravenous Immune Globulin (IVIG)
Demonstration
CMS–10340 Collection of Encounter
Data from MA Organizations
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
1. Type of Information Collection
Request: Extension without change of a
currently approved collection; Title of
Information Collection: Application for
Participation in the Intravenous
Immune Globulin (IVIG) Demonstration;
Use: Traditional fee-for-service (FFS)
Medicare covers some or all components of
home infusion services depending on the
circumstances. By special statutory provision, Medicare
Part B covers intravenous immune
globulin (IVIG) for persons with primary immuno
deficiency disease (PIDD) who
wish to receive the drug at home.
However, Medicare does not separately
pay for any services or supplies to
administer it if the person is not
homebound and otherwise receiving
services under a Medicare Home Health
episode of care. As a result, many
beneficiaries have chosen to receive the
drug at their doctor’s office or in an
outpatient hospital setting.
The Medicare IVIG Demonstration
application requests basic demographic
information necessary to determine
eligibility for participation in the
demonstration. This information is used by
CMS’ implementation support
contractor to determine eligibility for
the demonstration and to set up a
demonstration eligibility record that is
used by the Medicare claims system
when processing claims for
demonstration services.
The application also includes some
questions about how and where the
beneficiary is currently receiving
immunoglobulin and related services.
This data is being used by the
evaluation contractor to conduct its
evaluation and to better understand