

space with tools for posting, receiving, controlling and analyzing their data; an easy-to-use data display dashboard; and a shared environment where users can collaborate and advance public health surveillance practice. Each site is responsible for creating its own data use agreements with the facilities that are sending the data, retains ownership of any data it contributes to its exclusive secure space, and can share data with CDC or users from other sites.

NSSP has three different types of information collection:

(1) Collection of onboarding data about healthcare facilities needed for state, local, and territorial public health

departments to submit EHR data to the BioSense Platform;

(2) Collection of registration data needed to allow users access to the BioSense Platform tools and services; and

(3) Collection of data sharing permissions so that state and local health departments can share data with other state and local health departments and CDC.

Healthcare data shared with CDC can include: EHR data received by state and local public health departments from facilities, including hospital emergency departments and inpatient settings, urgent care, and ambulatory care; laboratory tests ordered and their results

from LabCorp, a national private sector laboratory company; and EHR data from the Department of Defense (DoD) and the Department of Health and Human Services (HHS) National Disaster Medical System (NDMS) Disaster Medical Assistance Teams (DMATs).

Respondents include state, local, and territorial public health departments. There are no costs to respondents other than their time to participate. The only burden incurred by the health departments are for submitting onboarding data about facilities to CDC, submitting registration data about users to CDC, and setting up data sharing permissions with CDC. The estimated annual burden is 195 hours.

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)
State, Local, and Territorial Public Health Departments.	Onboarding	10	100	10/60	167
State, Local, and Territorial Public Health Departments.	Registration	10	15	10/60	25
State, Local, and Territorial Public Health Departments.	Data Sharing Permissions	10	1	15/60	3
Total	195

Jeffrey M. Zirger,

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

[FR Doc. 2019-05188 Filed 3-19-19; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10553]

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 May 20, 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.

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–10553 Medicaid Quality Assessment and Performance Improvement Programs, State Review of Accreditation Status, Medicaid Managed Care Quality Rating System, and Quality Strategy (QS) and Supporting Regulations

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 of a currently approved collection; *Title of Information Collection:* Medicaid Quality Assessment and Performance Improvement Programs, State Review of Accreditation Status, Medicaid Managed Care Quality Rating System, and Quality Strategy (QS) and Supporting Regulations; *Use:* Medicaid beneficiaries and stakeholders use the information collected and reported to understand the state’s quality improvement goals and objectives, and to understand how the state is measuring progress on its goals. States use this information to help monitor and assess the performance of their Medicaid managed care programs. This information may assist states in comparing the outcomes of quality improvement efforts and can assist them in identifying future performance improvement subjects. CMS uses this information as a part of its oversight of Medicaid programs. *Form Number:* CMS–10553 (OMB control number: 0938–1281); *Frequency:* Yearly and occasionally; *Affected Public:* Private sector (business or other for profits) and State, Local, or Tribal Governments; *Number of Respondents:* 603; *Total Annual Responses:* 6,441; *Total Annual Hours:* 52,343. (For policy questions regarding this collection contact Barbara Dailey at 410–786–9012.)

Dated: March 15, 2019.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2019–05267 Filed 3–19–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1918]

Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis; 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 final guidance for industry entitled “Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.” The purpose of this guidance is to provide to sponsors nonclinical and clinical recommendations specific to the development of systemic drug products, with a focus on long-acting systemic drug products (including small molecules and monoclonal antibodies). This guidance incorporates the comments received for and finalizes the draft guidance of the same name issued in June 2018.

DATES: The announcement of the guidance is published in the **Federal Register** on March 20, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–1918 for “Human Immunodeficiency Virus-1 Infection: Developing Systemic Drug Products for Pre-Exposure Prophylaxis.” 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 <https://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