DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-23-23GL; Docket No. CDC-2023-0055]

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 National Wastewater Surveillance System for COVID-19 and other infectious disease targets of public health concern. The proposed information collection project aims to collect pathogen and public health target concentration in wastewater, wastewater target variant sequencing data, sewershed spatial files, and associated sewershed-level case data from participating jurisdictions in the United States to inform infectious disease prevention and control efforts.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2023-0055 by either of the following methods:

- Federal eRulemaking Portal: www.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 H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.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 H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: 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;

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; and
5. Assess information collection costs.

Proposed Project

National Wastewater Surveillance System for SARS-CoV-2 and other infectious disease targets of public health concern – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This information collection request is built upon a project currently approved under the COVID-19 Public Health Emergency (PHE) PRA Waiver. This expanded information collection request is for three years. The COVID-19 pandemic has demonstrated the need for timely, actionable surveillance data to inform disease prevention and control activities. The genetic material of SARS-CoV-2, the virus that causes COVID-19, has been detected in the feces of infected individuals, regardless of their symptom status. Therefore, sampling and testing wastewater provides a means to assess SARS-CoV-2 infection trends in the community independent of clinical testing or other healthcare indicators. This public health surveillance approach can be used for other infectious diseases or targets, such as mpox, influenza, and antimicrobial resistance. Recommendations for wastewater data collection for specific infectious diseases will be based on public health need and input from the NWSS Advisory Council comprised of subject matter experts from across CDC.

The Waterborne Disease Prevention Branch (WDPB) in the Division of Foodborne, Waterborne, and Environmental Diseases works to prevent domestic and global water, sanitation,

and hygiene related disease. In support of the Centers for Disease Control and Prevention (CDC) COVID-19 response, WDPB established the National Wastewater Surveillance System (NWSS). NWSS serves as a public health tool to provide wastewater surveillance of SARS-CoV-2 infections. In 2022, NWSS was expanded to include environmental surveillance of mpox infections. NWSS was designed to permit the addition or exchange of targets for wastewater infectious disease testing. This built-in flexibility will allow jurisdictions to adapt wastewater testing to changing public health needs, enable rapid responses to outbreaks or emergencies, and support broad capacity to detect future disease threats. Wastewater data have provided impactful information to local public health authorities, whether to confirm trends observed in testing or hospitalization rates, or to assert the need for increased testing or healthcare resources. NWSS has supported jurisdictions throughout the United States to implement wastewater surveillance, and will continue to support state, tribal, local, and territorial (STLT) partners to collect wastewater data. Together with CDC-funded national-level wastewater testing, jurisdictions across the U.S. have submitted data to NWSS that represents approximately 138 million individuals, or 41% of the U.S. population. Data are input to the Data Collation and Integration for Public Health Event Response (DCIPHER) platform for participants to view and analyze in near real time.

Wastewater surveillance provides aggregated, anonymized data at the community level to indicate trends in infections. These data can be especially impactful in underserved populations where clinical testing is limited or health care seeking is reduced. Wastewater data collection could inform locations that require greater resource allocation early in outbreaks and provide health departments with additional surveillance data to assess community-level infection trends. Wastewater data collection will be coordinated by health department jurisdictions through close collaboration with wastewater utilities, testing laboratories, and by CDC through national-level testing contracts that cover up to 500 wastewater utility sites. There are three data components comprising this collection request. For data collection Component 1, wastewater utilities or

partners will collect single time point, time-weighted composite, or flow-weighted composite samples from wastewater influent lines or at other points in the collection stream at regular intervals, such as once a week. The wastewater samples will be shipped, along with their associated sampling metadata, to testing laboratories where pathogen- or target-specific RNA or DNA will be quantified for up to 30 targets (e.g., SARS-CoV-2, mpox, influenza, antibiotic resistance, etc.). For some wastewater samples, target sequencing will be conducted to help public health officials monitor infectious disease variant trends (e.g., SARS-CoV-2). The testing laboratory will deliver wastewater sample collection and laboratory testing data to the jurisdiction health department, or directly to the CDC from national-level testing, to compile, review, and submit to CDC through the NWSS DCIPHER platform.

For data collection Component 2, jurisdiction health departments will work with participating utilities to obtain spatial files of the utility service areas, also called a sewershed. These sewershed spatial files will be uploaded by jurisdiction health departments into the NWSS DCIPHER platform.

For data collection Component 3, health department jurisdictions may choose to develop a line list of reported cases of specific infections (e.g., COVID-19, mpox, influenza, antibiotic resistant infections, etc.) associated with the participating wastewater utility service areas. The health department jurisdiction will submit to CDC the line list of deidentified cases into the NWSS DCIPHER platform.

The proposed data collection will occur over three years. Based on previous pilot data collection and additional estimates from 2022-2023 U.S. case numbers in the CDC National Notifiable Disease Surveillance System (NNDSS), it is estimated that 166,400 wastewater samples and 2,198,736 sewershed-level case data files will be collected and reported to NWSS each year, while 1,100 sewershed spatial files will only need to be submitted once during the three-year period. In total, the estimated annual burden for all data collection components for this request is 571,013 hours.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
State, tribal, local, territorial health departments	Component 1 Forms: NWSS Data Dictionary v5.0.0 CDC Seq Manifest Data Dictionary BioSample_WW Template v1.9 SRA Template v5.7 NWSS NCBI DCIPHER Crosswalk_Data Dictionary NWSS_DCIPHER Wastewater Data CSV Upload Template Component 1-2-3 NWSS DCIPHER CSV Bulk Upload Tool	55	2,080	139/60	265,026
Private laboratory	Component 1 Forms: Component NWSS Data Dictionary v5.0.0 CDC Seq Manifest Data Dictionary BioSample WW Template v1.9 SRA WW Template v5.7	1	52,000	139/60	120,467

	NCBI DCIPHER Crosswalk Data Dictionary NWSS DCIPHER Wastewater Data CSV Upload Template v3 Component 1-2-3 NWSS DCIPHER CSV Bulk Upload Tool				
State, tribal, local, territorial health departments	Component 2 Forms: Sewershed Spatial Files (No Form) Component 1-2-3 NWSS DCIPHER CSV Bulk Upload Tool	55	20	5/60	92
Wastewater utilities	Component 2 Forms: Sewershed Spatial Files (No Form) Component 1-2-3 NWSS DCIPHER CSV Bulk Upload Tool	1100	1	2	2,200
State, tribal, local, territorial health departments	Component 3 Forms: NWSS COVID Case Data Dictionary NWSS DCIPHER Case Data CSV Upload Template NWSS DCIPHER Sewershed Name Crosswalk CSV Upload Template Component_1-2-3 NWSS DCIPHER	55	39,977	5/60	183,228

	CSV Bulk Upload Tool				
Total					571,013

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.

[FR Doc. 2023-14413 Filed: 7/6/2023 8:45 am; Publication Date: 7/7/2023]