

National Outbreak Reporting System

Request for Revision

OMB No. 0920-1304

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Supporting Statement A

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- **Goal of the study:** The National Outbreak Reporting System (NORS) is a web-based platform that is used by local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to CDC.
- **Intended use of the resulting data:** CDC analyzes outbreak data to determine trends and develop and refine recommendations for prevention and control of foodborne, waterborne, and enteric disease outbreaks.
- **Methods to be used to collect:** State, local, and territorial health departments in the US submit data on outbreaks to CDC through NORS on an ongoing basis, through a secure, web-based platform.
- **The subpopulation to be studied:** All state, local, and territorial health departments in the US can submit data to CDC on waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission, that occur in the United States.
- **How data will be analyzed:** Data are cleaned and aggregated annually and included in surveillance summaries, scientific publications, as well as made publicly available on the NORS Dashboard website.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests changes to the National Outbreak Reporting System (NORS), approved under OMB Control No. 0920-1304. NORS is a core surveillance activity at CDC. Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service since 1878. Through the years, PHS/CDC has formulated practical methods of disease control through field investigations. The CDC surveillance program is based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. Over the years CDC's mandate has broadened to include preventive health activities thus expanding surveillance systems. This surveillance program is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241) (Attachment 1).

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologists (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. In 1968, at the beginning of this surveillance program, CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health. Surveillance forms are distributed to state and local health department staff who voluntarily submit reports to CDC. Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments must be able to share data on certain diseases across jurisdictions and to coordinate program activities to prevent and control illness. NORS collects data on all waterborne and foodborne disease outbreaks and

enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. Though reporting to NORS is voluntary, NORS serves as the platform by which state, local, and territorial health departments submit data on foodborne and waterborne disease outbreaks, which are nationally notifiable. By analyzing data reported through NORS, CDC can better characterize such outbreaks and develop recommendations for prevention and control.

CDC requests OMB approval to combine the two NORS forms (Form 52.12 Waterborne Disease Transmission and Form 52.13 Foodborne, Person to Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission mode) into one form (Form 52.14, Attachment 4). This change will streamline the data elements that are collected, by resulting in the utilization of one form for all reportable modes of transmission and eliminating overlapping data collection fields. All data are collected via the NORS online data entry system, and while all possible data elements are detailed in the data dictionary (Attachment 3), reporters completing the NORS form via the online data entry system will only see applicable questions based on mode of transmission. Form 52.14 is the reference document; no data are submitted to CDC via paper copy.

2. Purpose and Use of Information Collection

State, local, and territorial epidemiologists are responsible for the collection, interpretation, and transmission of epidemiologic information at the state level. Health departments submit data collected through routine outbreak investigations to CDC, and CDC tabulates, analyzes the data for trends, publishes, and distributes the data both publicly and through analyses within the scientific community. By coordinating nationwide collection of epidemiological data, CDC can determine both national and state-specific estimates and comparisons of foodborne, waterborne, and enteric disease outbreaks.

NORS data are collected electronically, through a password-protected, web-based platform hosted by CDC. Attachment 3 is the data dictionary for the NORS platform and details all possible data elements. Attachment 4 is the reference tool for NORS. The reference tool is used to assist users with data collection for NORS and outlines the data elements collected for investigations of all foodborne and waterborne disease outbreaks, as well as enteric disease outbreaks caused person-to-person transmission, animal contact, environmental contamination, and those that were spread by an unknown mode of transmission.

Data collected through NORS are essential for measuring trends in foodborne, waterborne, and enteric disease outbreaks, evaluating the effectiveness of current preventive strategies, and determining the need to modify current preventive measures. Data on outbreaks for which NORS reporting is applicable can be transmitted to CDC at any time. Rapid reporting is encouraged as soon as officials are notified of the outbreak, as this timely reporting is helpful for control of outbreaks, understanding of any pathogen-specific trends, and development of recommendations for prevention. NORS data may thus enable rapid detection and characterization of outbreak-associated pathogens and vehicles of transmission.

The burden for data collected through NORS is estimated at 20 minutes per form or approximately 1,160 burden hours. There are no costs to the respondents other than their time.

3. Use of Improved Information Technology and Burden Reduction

Historically, use of outbreak data collected by the Foodborne Disease Outbreak Surveillance System and the Waterborne Disease and Outbreak Surveillance System were slowed because of the time required for data entry and analyses once the forms were received. In 1998, CDC introduced electronic reporting of foodborne outbreak data through the electronic Foodborne Outbreak Reporting System (eFORS). eFORS was a web-based reporting system used by local, county, or state organizations to enter, edit, analyze, and transmit data electronically to other state or federal offices. Beginning in 1998, all foodborne outbreak reports were entered into eFORS. In 2009, this system was phased out in lieu of the National Outbreak Reporting System (NORS). NORS was designed to integrate the outbreak reporting systems and enhance national outbreak reporting by allowing for ongoing reporting of all foodborne and waterborne disease outbreaks, as well as enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission. All data are collected electronically through the NORS web-based platform.

Attachment 3 is the data dictionary for the NORS platform. Attachment 4 (NORS Foodborne Disease Transmission, Waterborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.14) is the reference tool for NORS. State, local, and territorial health departments may use form 52.14 to assist in gathering information for submission to NORS, however no data are submitted to CDC using paper forms; all data must be submitted electronically. The information requested is the minimum amount required to maintain surveillance for foodborne, waterborne, and enteric disease outbreaks.

4. Efforts to Identify Duplication and Use of Similar Information

The specific variables included in this information collection request are not included in any other nationwide outbreak-specific surveillance system. While similar information may be collected from limited geographic areas or collected in one-time studies, for most outbreaks, sampling would not be sufficient for state prevention and control programs. NORS collects outbreak data from all U.S. states and territories in a uniform manner.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Outbreak reporting varies to the extent that pathogens differ in occurrence, modes of transmission, infectious agents, patient's susceptibility and resistance, control of patient's contacts and the immediate environment, and epidemiologic measures. The first step in the control of a given outbreak is its rapid identification followed by notification to the local health authority. Prompt notification to CDC allows for further identification of any larger-scale outbreaks as well as any potential increase in pathogen prevalence during a given time period, so that prevention and control measures can be taken. Outbreaks caused by various pathogens are reported with varying frequency to CDC as they occur. Since NORS

was established in 2009, approximately 2,000–4,500 outbreaks have been reported to CDC each year.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

As described in section A.6, in order to permit rapid response to outbreaks and timely initiation of prevention and control measures, health departments are encouraged to report outbreak data to CDC as soon as possible after identification of the outbreak. As outbreaks may occur at any time, reporting may occur more or less frequently than once per quarter and outbreak investigations may take several weeks to months to finalize. Given this, reports may be entered into NORS and/or edited at any time in order to allow for all available information to be reported to CDC, and delays in reporting could potentially result in serious public health consequences. There are no other special circumstances. This request fully complies with regulation 5 CFR 1320.5 with the exception to quarterly reporting.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A 60-day Federal Register Notice was published in the Federal Register on October 13, 2021, vol. 86, No. 195, pp. 56957 (Attachment 2). CDC did not receive any comments.
- B. The Council of State and Territorial Epidemiologists (CSTE) are routinely consulted regarding the availability of data, the frequency of collection, and the revisions of any forms. CDC has collaborated with CSTE since CSTE's inception in 1951, and it is through the CSTE annual conference that the cooperation of all states is maintained. Although formal CSTE meetings are usually held only once a year, communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis throughout the year.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The NCIRD Information Systems Security Officer reviewed this submission and determined that it is not applicable to the Privacy Act because the information is not retrieved by personal identifiers. PII related to outbreak surveillance is not submitted to CDC. Non-personally identifiable data relating to foodborne, person-to-person, animal contact, environmental, unknown, and waterborne outbreaks are submitted in aggregate to CDC via NORS. The NORS platform is housed in a secure system; only those users with password-protected accounts may access and/or enter NORS data.

Records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to use the records. Any paper or computer files are stored according to state and local health department privacy standards; paper files are not submitted to CDC.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Institutional Review Board (IRB)

IRB Approval

A CDC human subjects advisor has determined that the activities in 0920-1304 (Attachments 3 and 4) are considered routine public health surveillance activities. Consistent with current CDC policy, routine surveillance activities do not meet the regulatory definition of research and are therefore outside the scope of IRB review requirements.

Sensitive Questions

Epidemiologic characteristics such as age, sex, and geographic location, as well as clinical laboratory data are routinely collected because of their significance in resolving public health problems. All outbreak data are collected in aggregate, and only the minimum data necessary for public health surveillance are collected.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

State, local, and territorial epidemiologists report data to CDC through NORS. The estimated number of annualized burden hours is expected to increase by 413 hours, from 747 hours to 1,160 hours. This change is due to an increase in the median number of reports submitted by respondents, as estimated based on reports submitted for 2019. The frequency of response for the NORS form is dependent on outbreak activity in the United States, varies depending on the pathogen and surveillance need, and often fluctuates each year. The proposed changes do not affect the burden per response, which was estimated at approximately 20 minutes per form, based on the average time to complete the common data collection fields by multiple team members. Attachment 4 is the reference tool for attachment 3 and reflects 0 burden hours.

| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
|--------------------|--|--------------------|------------------------------|------------------------------------|------------------------|
| Epidemiologist | Attachment 3_National Outbreak Reporting System, Data Dictionary | 59 | 59 | 20/60 | 1,160 |
| | Attachment 4_Form 52.14 | | | | |
| Total | | | | | 1,160 |

B. Estimated Annualized Burden Costs

The proposed estimated annual cost for the NORS form is \$41,574.40. This is based on the 2020 median hourly wage of \$35.84 for an epidemiologist, as indicated on the Bureau of Labor Statistics website (<https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm>). This reflects an increase of \$16,557.37 from the approved respondent cost of \$25,017.03 . The increase in cost is due to the increase in median hourly wage for an epidemiologist (previously reported as \$33.49 based on 2018 data), as well as the increase in burden hours due to an estimated increase in the median number of submitted reports. Attachment 4 is a reference tool for attachment 3 and reflects \$0 cost burden.

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hours) | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|--------------------|--|--------------------|---------------------------------|-------------------------------------|--------------------|------------------|------------------------|
| Epidemiologist | Attachment 3_National Outbreak Reporting System, Data Dictionary | 59 | 59 | 20/60 | 1,160 | \$35.84 | \$41,574.40 |
| | Attachment 4_Form 52.14 | | | | | | |
| Total | | | | | | | \$41,574.40 |

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital and maintenance costs incurred by respondents other than their time to participate.

14. Annualized Cost to the Government

Outbreak reports submitted to CDC result in action taken by multiple programs in response to the required CDC mandate to maintain preventive health activities and surveillance systems. Actions taken in response to each report will vary, depending on the specifics of the outbreak. NORS activities (Attachment 4, which encompasses activities in Attachment 3) cost an estimated \$1,285,000.00. The foodborne and waterborne estimates include approximately \$900,000.00 for personnel across two CIOs (NCIRD and NCEZID) and approximately \$350,000.00 for Information Technology. The overall incurred costs include staff support, NORS platform maintenance, computer resources, and some printing and miscellaneous expense such as phone calls.

15. Explanation for Program Changes or Adjustments

This is a request to combine the two currently approved forms (Form 52.12 Waterborne Disease Transmission and Form 52.13 Foodborne, Person to Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission mode) previously approved under OMB Control No. 0920-1304 into one form (Form 52.14, Attachment 4). This change will streamline the data elements that are collected, by resulting in the utilization of one form for all reportable modes of transmission and eliminating overlapping data collection fields. The collection activities as previously approved in 0920-1304 remain the same. The changes primarily consist of label changes that will improve clarity and accuracy of the data collected. Additionally, existing questions have been re-organized and moved into newly named sub-sections in order to facilitate completion of the form. These label changes and reorganizations do not impact the burden on reporters and should result in improved readability. Some sections have also been added to the form for specific modes of transmission, in order to improve outbreak surveillance by increasing data quality to inform prevention efforts. Existing questions have been moved into these newly proposed sections, and some new questions have been added to improve data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

NORS data are collected on an ongoing basis and undergo a rigorous cleaning process with state submitters approximately once a year, per mode of transmission. Cleaned data are published periodically in surveillance summaries, as part of MMWR, and included in various program specific analyses. In addition, a subset of cleaned data are made available annually on the NORS Dashboard (<https://wwwn.cdc.gov/norsdashboard/>); larger datasets are available to the public upon request to CDC.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

NORS data are collected through a web-based platform, for which Attachment 3 is the data dictionary, and Attachment 4 is the reference tool. Since the original approval of 0920-1304, modifications have been made to the information collection instrument. Because of their long period of use, printed paper forms are still in use at some health departments. No data are submitted to CDC using the paper forms; all data must be submitted electronically. As such, permission is requested to exclude the expiration date from the NORS forms.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing legislation - Section 301 of the Public Health Service Act (42 USC 241)
2. Published 60-day FRN
3. Information Collection Instrument, Data dictionary for the National Outbreak Reporting System

4. Reference tool, NORS Foodborne Disease Transmission, Waterborne Disease Transmission, Person-to-Person Disease Transmission, Animal Contact, Environmental Contamination, Unknown Transmission Mode, Form 52.14
5. Descriptive summaries for activities included in the National Outbreak Reporting System