Generic Clearance for the Collection of Minimal Data Necessary for Case Data During an Emergency Response

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Supporting Statement A

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Minimal Data Necessary for Case Data During an Emergency Response

Goal of the study: The Minimal Data Necessary (MDN) for Case Data During an Emergency Response generic information collection request (ICR) is specifically designed to collect the MDN and response-specific data as needed, for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response at CDC. During an emergency response, CDC uses case data to inform actions that need to be taken at all levels of public health and by the public. State, tribal, local, and territorial (STLT) health departments and CDC need to exchange data on confirmed, probable, and suspected cases rapidly. Timely notification of cases from STLT to CDC is critical to provide situational awareness at the federal level to support decision making, particularly for public health threats that escalate quickly and cross jurisdictions. Case data for each generic information collection (GenIC) will be collected for the duration of this generic ICR's approval. If collection of case data is required after the approval period for this generic ICR is over, CDC will submit a new GenIC.

Intended use of the resulting data: Data will be used for ongoing situational awareness and to monitor the occurrence and spread of the disease or condition. Other uses may include identifying populations or geographic areas at high risk; planning prevention and control programs and policies; and allocating resources appropriately. The data may also be used by CDC to obtain travel histories and other information to describe and manage outbreaks and conduct public health follow-up to minimize the spread of disease.

Methods to be used to collect: Data will be sent to CDC by STLT health departments through the Data Collation and Integration for Public Health Event Response (DCIPHER) system. Other automated or non-automated mechanisms including but not limited to fax, email, secure file upload, and data entry to a secure website may also be used under limited circumstances.

The subpopulation to be studied: The respondent population consists of 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

How data will be analyzed: Case counts will be aggregated by various demographic and geographic factors.

1. Circumstances Making the Collection of Information Necessary

Background. The Centers for Disease Control and Prevention (CDC) is requesting Office of Management and Budget (OMB) approval for a new generic information collection request (ICR) to collect the MDN and response-specific data as needed for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response at CDC, for a 3-year period.

The MDN is an integral part of CDC's Data Modernization Initiative (DMI), a multi-year, multi-billion-dollar effort launched in 2020 to modernize data across the federal and state public health landscape. The goal of DMI is to enable better, faster, actionable insights for decision-making at all levels of public health. DMI is further supported by the Public Health Data Strategy (PHDS), CDC's mission-focused, goal-driven, two-year plan providing accountability for data, technology, policy, and administrative actions necessary to meet public health data goals. The PHDS milestones address challenges in data exchange between healthcare organizations and public health authorities and between State, tribal, local, and territorial (STLT) and federal public health authorities.

The MDN for case notification data is being implemented in 2024 through the Response Readiness for Case Data (RRCD) project. The purpose of the RRCD project is to operationalize the MDN by:

- Securing appropriate endorsements for the MDN as the foundation for a new agency-wide approach to collecting case data in a response,
- Developing an efficient process for proposing, defining, and implementing data elements that may be needed for a particular response, and
- Defining and aligning an implementation plan to drive wide-spread adoption among CDC programs and public health jurisdictions.

Evidence of support for and progress toward implementation of the MDN is demonstrated by the following:

- Section 319D of the Public Health Service Act (as amended Through P.L. 118-35, enacted January 19, 2024) states: "CDC shall define the minimum data necessary as the Agency collaborates with STLTs and other partners to improve the appropriate near real-time electronic transmission of interoperable public health data for situational awareness and response to public health emergencies" **[Attachment 1. Authorizing Legislation]**.
- H.R.2882 - Further Consolidated Appropriations Act, 2024 - became Public Law No: 118-47 on March 23, 2024. Relevant joint explanatory text (report language) states: "Public Health Data Modernization. The agreement urges CDC to work with representatives from STLT health departments through a regular convening mechanism to establish a public health data sharing process to ensure that notifiable case data are reported to CDC during an emergency response event in a timely and efficient manner that is the least burdensome for STLT public health departments. This process should include the use of an established minimal data set and transmission via existing and automated reporting mechanisms to the extent possible."

- The November 2022 CDC Advisory Committee to the Director Data and Surveillance Workgroup report recommended that CDC and partner organizations "define the minimal data necessary for core public health data sources."
- The 2022-2023 DMI implementation plan directed CDC to "define data requirements for case-level situational awareness from day one of a public health emergency." Subsequently, between August 2022 and February 2023, a cross-agency effort took a consensus-based approach to define the MDN with CDC and partner organizations.
- The April 2023 PHDS defines case data as a core data source and lists as part of its fourth goal ("to advance more open and interoperable public health data") that a set of minimal data elements for case data should be established in collaboration with STLT partners and CDC programs. Once implemented, CDC programs will be able to syndicate and collect a standardized set of data elements for case data, reducing reporting burden for STLT partners.
- The Council of State and Territorial Epidemiologists (CSTE) garnered broad support among STLTs for a minimum data set to enable response situational awareness.

Each generic information collection (GenIC) under this generic ICR will be implemented at the beginning of an emergency response and case data will be collected for the duration of this generic ICR's approval. The respondent population for each GenIC will consist of 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). Each GenIC will include a detailed description of the disease or condition that is the subject of the emergency response, why case data are needed, and what the case data will be used for. The MDN will be collected for each GenIC with the option to include response-specific data elements. Justification will be provided for each response-specific data element included.

This generic ICR includes a request to approve GenICs within 72 hours to 5 days to ensure timely information collection required during an emergency response. During an emergency response, CDC needs case data to mobilize quickly and take immediate action alongside STLT partners to minimize or prevent public harm. CDC must have the ability to rapidly collect data to understand the scope of the problem and determine appropriate action.

Need. The development and implementation of this generic ICR is urgent. CDC would like to use this generic ICR for the next emergency response. Use of the process in this generic ICR would have expedited the approval process for the 2019-2023 COVID-19 and 2022 and 2024 Mpox emergency responses. The current OMB approval process for case notification data collection during an emergency is decentralized, incumbent on each Center to manage, does not include a review of data elements and value sets for alignment with Agency-wide standards, and must be done in an accelerated and expedited process over the weekend or after hours, and across multiple offices. This proposed generic ICR is a more predictable approval process for collection that will be standardized across the Agency.

This generic ICR covers case data collected during any emergency response at CDC.

2. Purpose and Use of Information Collection

The purpose of this generic ICR is to collect the MDN and response-specific data as needed for confirmed, probable, and suspected cases of any disease or condition that is the subject of an emergency response at CDC. Timely notification of cases from STLT to CDC is critical to provide situational awareness at the federal level to support decision making, particularly for public health threats that escalate quickly and cross jurisdictions. Case data are needed to ensure that CDC receives sufficient information to develop and implement effective prevention and control strategies to minimize adverse health consequences. To accomplish this objective, case data must be collected rapidly.

The MDN includes 54 standardized data elements that describe the "who" (e.g., number of people affected, demographics, pregnancy status, underlying medical conditions, hospitalization status), the "what" (e.g., condition and category, symptoms, laboratory tests), the "when" (dates of symptom onset, diagnosis, laboratory results, case occurrence, death, date entered into STLT system, date sent to CDC), the "where" (e.g., jurisdiction), and the "why" (e.g., link to known outbreaks, relevant exposures, travel history). The complete list of MDN data elements is identified in an attachment **[Attachment 3. List of MDN Data Elements for Case Data During an Emergency Response].**

A negative consequence of not having the information is increased or sustained morbidity and mortality associated with the disease or condition that is the subject of the emergency response at CDC. Rapid disease notification is an indispensable tool for CDC officials to monitor the occurrence and prevent the spread of the diseases during an emergency response. Timely assessment is critical, particularly for emerging disease threats.

3. Use of Improved Information Technology and Burden Reduction

Case data will be sent to CDC by STLT health departments through a common operating platform via the Data Collation and Integration for Public Health Event Response (DCIPHER) interface. DCIPHER is a secure, scalable tool used to collate, prepare, analyze, and visualize case notification data. DCIPHER can connect to virtually any system or data source, enabling data integration agnostic of source or format, and providing near real-time insights into public health problems. DCIPHER's capabilities align with the PHDS goals to strengthen the core of public health data, accelerate access to analytic and automated solutions to support public health investigations and advance health equity, visualize and share insights to inform public health action, and advance more open and interoperable public health data.

DCIPHER collects data directly via forms, spreadsheets, or machine-to-machine transfer and can receive data from any system. DCIPHER has been used to support emergency responses including E-Cigarette or Vaping Product Use-Associated Lung Injury (EVALI) and COVID-19. For EVALI, DCIPHER moved from concept to full roll-out (inclusive of a two-week pilot) to 53 states/jurisdictions in just five weeks. The EVALI team leveraged DCIPHER as their common operating platform to automate and standardize the entirety of the data management lifecycle and reduced the number of resources required to support data management activities by 75%,

allowing for data preparation and consolidation to be completed within hours, rather than days. For COVID-19, DCIPHER was scaled rapidly to support 900 users, and ingestion of 47 datasets. This included the daily production of the main COVID-19 case surveillance dataset, which included 23+ million records. These examples illustrate how the use of DCIPHER can ease the reporting burden of jurisdictions that send case data to CDC during emergency responses.

While DCIPHER will be the common operating platform and main data collection tool used to collect case data during emergency responses, jurisdictions may use other automated or non-automated mechanisms to send case data to CDC under very limited circumstances. These mechanisms include but are not limited to fax, email, secure file upload, and data entry to a secure website. This flexibility reduces the burden on the jurisdictions.

The burden on jurisdictions is reduced by allowing them to use transmission methods that are already set up and automated. Many jurisdictions have already onboarded the Generic Version 2 (GenV2) Message Mapping Guide (MMG) and are able to connect their surveillance system to CDC to send GenV2 data elements with no additional burden incurred. There is a total of 67 GenV2 data elements and of the 67 GenV2 data elements, 42 are not MDN data elements **[Attachment 4. List of GenV2 Data Elements that are not MDN Data Elements]**. If the condition that is the subject of an emergency response is nationally notifiable, permission for CDC to collect GenV2 data elements from jurisdictions is already covered by the ICR 0920-0728, National Notifiable Diseases Surveillance System (NNDSS). However, if the condition that is the subject of the emergency response is not nationally notifiable, there is no existing ICR that grants permission for CDC to collect GenV2 data elements. Therefore, in addition to permission to collect MDN and response-specific data elements for conditions that are nationally notifiable and conditions that are not nationally notifiable, CDC requests permission under this generic ICR to collect GenV2 data elements for conditions that are the subject of an emergency response and are not nationally notifiable.

CDC is committed to minimizing the disease collection and submission burden for jurisdictions. This will be accomplished by:

- Helping jurisdictions focus their surveillance efforts by providing guidance on which data elements are most important for situational awareness.
- Not requiring jurisdictions to send data elements that are not available for an individual case, not included in the jurisdiction's surveillance system, or not a priority for collection in the jurisdiction; and
- Receiving these data through DCIPHER, an existing infrastructure that supports automated messaging and that is already in use by public health jurisdictions to transmit case data from their jurisdiction surveillance systems to CDC.

To further support the use of improved information technology, aggregate case data from each emergency response may be available to the public on https://data.cdc.gov and https://data.gov.

4. Efforts to Identify Duplication and Use of Similar Information

No other Federal agency funds or conducts this type of surveillance based on information on confirmed, probable, and suspected cases of diseases or conditions that are the subject of an emergency response. This information obtained from STLTs and maintained by CDC serves as a unique, centralized, integrated source of information in the U.S. and the information is not available from any other source. While there are current ICRs in use by CDC to facilitate data collection during emergencies, there is no standard mechanism to collect the MDN and response-specific case data for diseases or conditions that are the subject of an emergency response at CDC.

A CDC staff person will serve in the role of MDN for Case Data Information Collection Request Liaison (ICRL). The ICRL will be responsible for maintaining a response-specific data element library, which will include a list of response-specific data elements and their value sets used under this generic ICR. These data elements can be reused during future emergency responses to ensure standardization and harmonization of case data.

5. Impact on Small Businesses or Other Small Entities

This submission of information does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

The frequency of notification of cases from STLT health departments to CDC during an emergency response is dependent on the disease or condition. Timely notification is critical to provide situational awareness at the federal level to support decision making, particularly for public health threats that escalate quickly and cross jurisdictions. Rapid transmission of case data is an indispensable tool for public health officials at CDC, who use the data to monitor the occurrence and prevent the spread of the diseases. Less frequent notification does not allow timely assessment, particularly for emerging disease threats. Changes in disease distribution are continuously monitored during the emergency response so that appropriate investigations or interventions may be rapidly undertaken. In addition, rapid transmission of case data is also necessary to allow the United States to meet its obligations under the 2005 International Health Regulations to report important events that meet the criteria to be considered a public health emergency of international concern to the World Health Organization.

Case data for each GenIC will be collected for the duration of this generic ICR's approval. If collection of case data is required after the approval period for this generic ICR is over, CDC will submit a new GenIC.

We are not aware of any legal obstacles to reducing the burden.

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

Collection of MDN and response-specific case data is conducted in a manner consistent with the guidelines in 5 CFR 1320.5. CDC requests that public health departments send case data to CDC as soon as possible, as justified under section A6.

To comply with the regulation 5 CFR 1320.5 and at the same time ensure that case data are collected in a timely manner as necessary to protect the health of the public, information collections using this generic ICR will adhere to the following timeline and processes:

1. CDC initiates an emergency response.
    a. CDC notifies HHS, the OMB-OIRA Desk officer, and his/her designated back up of the emergency response immediately via e-mail. The email will include: A statement that CDC cannot comply with normal clearance procedures because (i) public harm is reasonably likely to result if normal clearance procedures are followed, (ii) an emergency has occurred, and (iii) the use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information.
    b. The proposed timing of OMB's approval (between 72 hours and 5 days) and a justification for the proposed timing.
2. CDC sends the GenIC "MDN for Case Data During an Emergency Response Form" **[Attachment 5. MDN for Case Data During an Emergency Response Form]** to OMB-OIRA. This form includes an estimate of how long approval is needed, why CDC cannot reasonably comply with normal clearance procedures (i, ii, and iii above), a description of the disease or condition that is the subject of the emergency response (including whether it is nationally notifiable or under standardized surveillance), the initial response-specific data elements that will be collected, and how the collection is essential to the mission of CDC.
3. The OMB-OIRA Desk officer or designee responds with approval or comments on the proposed "MDN for Case Data During an Emergency Response Form" within the agreed upon approval period (between 72 hours and 5 days). OMB may provide approval and comments orally (followed by e-mail for written documentation) or e-mail directly to CDC. This may occur before the GenIC request is submitted and received by OMB through the official ICR tracking system. If no response is received within the agreed upon approval period, the information collection is considered OMB-approved.
4. At the completion of the emergency response, CDC emergency response staff submits the final list of response-specific data elements using the "Final Response-Specific Data Elements Form" **[Attachment 6. Final Response-Specific Data Elements Form]** to the ICRL.
5. CDC will maintain a list of all response-specific data elements collected under this generic ICR. This list will be submitted to OMB quarterly as a non-substantive change to the generic ICR.

A CDC staff person serves in the role of MDN for Case Data ICRL. The ICRL oversees the clearance process for individual GenICs. The ICRL maintains a list of response-specific data elements and value sets that may be utilized for future emergency responses. Upon the completion of an emergency response, the ICRL adds the response-specific data elements and value sets to the list. Each initial request is closely reviewed by the ICRL to ensure only GenICs for official CDC emergency responses are submitted to OMB for approval.

At this time, CDC is not able to change the race and ethnicity questions in this generic ICR to match the new OMB standard (SPD-15) as it will cause undue burden for the jurisdictions, cost to the government, and substantial delays in CDC's Response Readiness for Case Data project. Since CDC will not be collecting primary data for GenICs under this proposed generic ICR, CDC's ability to report accurate data for the required categories is dependent on the case data that the jurisdictions send to us. CDC does see the value of the new standard and plans to implement it in our next revision of the MDN Message Mapping Guide, estimated to occur by fall 2027.

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

A 60-day Federal Register Notice was published in the Federal Register on March 22, 2024, Vol. 89, No. 57, page 20476 **[Attachment 2a. 60-Day FRN]**. One non-substantive comment **[Attachment 2b. Public Comment]** was received. No changes were made to the supporting statement or data collection instruments.

9. Explanation of Any Payment or Gift to Respondents

Respondents receive no gift or payment for their participation in any information collections.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act applies to this ICR. The applicable SORN is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. Case data collected under this ICR will be stored in DCIPHER as CDC's common operating platform. DCIPHER is a cloud-based platform used across CDC, by other federal partners, and by state, local, tribal, and territorial public health jurisdictions to collect, collate, share, and link multiple sources of public health, outbreak, and event response data. It is designed to facilitate data interpretation and to inform public health decisions. DCIPHER operates in a FedRAMP-approved cloud environment and receives continuous deployment, upgrades, and patching.

Personally identifiable information (PII) is collected, and information can be retrieved by PII. However, information is not retrieved by PII. Jurisdictions remove most PII before data are submitted to CDC, but some data elements (e.g., date of birth, date of diagnosis, county of residence) could potentially be combined with other information to identify individuals. See the Privacy Impact Assessment (PIA) for DCIPHER **[Attachment 7. Data Collation and Integration for Public Health Event Responses (DCIPHER) Privacy Impact Assessment (PIA)]**. Private information will not be disclosed unless otherwise compelled by law. No assurance of confidentiality has been obtained.

As stated in Section A.3, aggregate case data from each emergency response may be available to the public on https://data.cdc.gov and https://data.gov. Privacy is protected in several ways. https://data.cdc.gov, and https://data.gov only provide summary statistics of aggregate data to their users. https://data.cdc.gov is also subject to and have met CDC's Security Assessment and

Authorization (SA&A) process through CDC's Office of the Chief Information Officer (OCIO). Only public use, non-PII data in the form of summary statistics are uploaded to https://data.cdc.gov per OCIO's policy. Data will be kept private to the extent allowed by law.

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

IRB Approval

This activity does not require Institutional Review Board (IRB) documentation as this activity is public health practice (surveillance), not research **[Attachment 8. MDN for Case Data During an Emergency Response Research Determination]**.

Sensitive Questions

There are no questions asked that are of a sensitive nature, but information is submitted about sensitive topics, including whether a patient has sexually transmitted diseases and sexual and drug-using behaviors. CDC must receive information about sensitive topics to monitor the occurrence of the diseases so that effective prevention and control programs can be planned and implemented.

12. Estimates of Annualized Burden Hours and Costs

CDC projects 10 emergency responses annually that will require states, territories, freely associated states, and cities to submit case data to CDC daily. Therefore, the following standard burden table (Table A1) will be used for each GenIC:

Table A1. Estimated Annualized Burden Hours per Response

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
States	Submission of case data	50	365	30/60	9,125
Territories	Submission of case data	5	365	30/60	913
Freely Associated States	Submission of case data	3	3650	30/60	548
Cities	Submission of case data	2	365	30/60	3,65
Total					10,951

The annual burden estimates below include the time that states, territories, freely associated states, and cities will incur to submit confirmed, probable, and suspected case data (MDN and response-specific data elements) for diseases or conditions for 10 emergency responses.

Table A2. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
States	Submission of case data	50	3650	30/60	91,250
Territories	Submission of case data	5	3650	30/60	9,130
Freely Associated States	Submission of case data	3	3650	30/60	5,480
Cities	Submission of case data	2	3650	30/60	3,650
Total					109,510

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2023 National Occupational Employment and Wage Estimates for the United States, the estimated mean hourly wage for Computer Systems Analysts is $53.27 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000). The estimated hourly wage for a Computer Systems Analyst is used for the submission of case surveillance data because this occupation represents the category of occupations held by the respondents that perform this activity. Using $53.72 as an average hourly wage rate for Computer Systems Analysts, it is estimated that the burden to submit case data for one year for 60 respondents is 109,510 hours at a national cost of $5,833,598.

Table B. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)	Hourly Wage Rate	Respondent Cost
States	Submission of case data	50	365	30/60	9,1250	$53.27	$4,860,888
Territories	Submission of case	5	365	30/60	9130	$53.27	$486,355

	data						
Freely Associated States	Submission of case data	3	365	30/60	5,480	$53.27	$291,920
Cities	Submission of case data	2	365	30/60	3,650	$53.27	$194,436
Total					109,510		$5,833,598

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

There are no anticipated costs to respondents other than time.

14. Annualized Cost to the Federal Government

The annual cost to the federal government includes personnel and other costs to maintain DCIPHER.

Table C. Estimated Annualized Cost to the Government

Item	Estimated Cost to Federal Government		
	FY 25 (projected)	FY 26 (projected)	FY 27 (projected)
DCIPHER – Personnel / Services (Contractors, FTEs)	$740,681	$740,681	$740,681
DCIPHER – Other (IT / Licensing)	$445,710	$445,710	$445,710
Total	$1,186,391	$1,186,391	$1,186,391

The estimated annualized cost to the government is $1,186,391 (average of three years).

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Each Information Collection (IC) under this proposed generic ICR will be implemented at the beginning of an emergency response and case data will be collected for the duration of the emergency response.

Summary statistics of aggregate case data from each emergency response may be available to the public on https://data.cdc.gov and https://data.gov.

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

CDC is not requesting an exemption to the display of the expiration date. CDC requests approval to place the PRA burden statement and OMB expiration date on the MDN for Case Data During an Emergency Response webpage. A screenshot of the webpage is shown in an attachment. **[Attachment 9. PRA Burden Statement Screenshot]**.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certifications statement.