

# **Undetermined cause of *Serratia marcescens* infections — Multiple States, 2018**

Request for OMB approval of a New Information Collection

**April 26, 2018**

## **Supporting Statement A**

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- **Goal of the study:** Identify medication and product exposures and other potential risk factors leading to *Serratia marcescens* infections among U.S. healthcare patients.
- **Intended use of the resulting data:** Identify a cause of the *Serratia marcescens* infections among U.S. healthcare patients and prevent additional events from occurring.
- **Methods to be used to collect:** Nationwide case-finding will be implemented (through Epi-X or professional email list). Information on cases identified through case finding may be submitted electronically to CDC via online secure submission form to CDC using the data collection form.
- **The subpopulation to be studied:** Respondents are state and local health department personnel reporting data for patients with *Serratia marcescens* infections in inpatient or outpatient settings.

• **How data will be analyzed:** Frequencies of product exposures will be calculated.

## 1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) requests an emergency 3-month approval for a New Information Collection, “Undetermined cause of *Serratia marcescens* infections — Multiple States, 2018.”

*Serratia marcescens* is a Gram-negative bacillus that can be found in the environment and thrives in moist environments. In healthcare settings, it can be found on the hands of healthcare workers and as a contaminant of medical products and devices, particularly aqueous products. It is a known cause of healthcare-associated infections, particularly urinary tract infection, wound infections, and bloodstream infections, and it is an important opportunistic pathogen in neonatal and pediatric intensive care units. *Serratia marcescens* has been implicated previously in multistate outbreaks of bloodstream infections caused by intrinsic contamination of prefilled syringes of heparin and isotonic sodium chloride solution.

On March 27, 2018, the Colorado Department of Public Health and Environment (CDPHE) notified CDC of 4 cases of *Serratia marcescens* bacteremia among pediatric patients with central lines in an acute care hospital between January 20 and March 23, 2018. This cluster of cases was above the normal baseline of 1–3 cases per year at that facility. The facility examined exposures including common staff and medications and identified commonalities related to the maintenance and care of central lines as well as several medical products including prefilled normal saline syringes and prefilled heparin flushes.

On March 28, CDPHE issued a call for cases to other state and local health departments through the Epidemic Information Exchange (Epi-X) system. On March 29, the Tennessee Department of Health (TDH) notified CDC of 3 cases of *Serratia marcescens* bacteremia in pediatric patients with central lines in a pediatric hospital between March 6 and March 21, 2018; initial examination of medications and common products identified central venous catheter line products as a possible source of infections, including prefilled heparin and normal saline syringes.

CDC is currently conducting a multistate investigation to support state health departments. Currently, eight state health departments have reported a total of 26 cases to CDC. However, since more than nine

states are ultimately expected to participate, CDC is pursuing emergency OMB clearance to collect patient-level information from ten or more state/local health departments.

Most identified patient infections are bloodstream infections, but other body sites (e.g., respiratory) have also been described. Because these events could be linked to a healthcare product (e.g., medical device or pharmaceutical product) with widespread distribution, broad case-finding efforts are needed. Early investigations identified prefilled normal saline syringes and prefilled heparin flushes as common exposures, however healthcare facility records often provide an inadequate basis for identifying the specific product or lot number that was administered to a particular patient, and only facility-level information is available. The products identified in common at this stage of the investigation are widespread in healthcare facilities across the United States and incorrect identification as the source of infections could reasonably be anticipated to create panic in regards to use of these products and limitations in the safe care delivered to thousands of patients.

Communications with the Food and Drug Administration (FDA) and product manufacturers indicate a nation-wide shortage of saline following disruption of manufacturing in Puerto Rico during Hurricane Maria in September 2017. FDA has stated that saline shortages in the U.S. mean that alternatives to prefilled saline are limited. In addition, the products are manufactured and subject to Current Good Manufacturing Practice regulations including terminal sterilization of many products using steam sterilization, which reduce opportunities for contamination.

This information is essential to the CDC's ability to identify a cause of these events and prevent additional events from occurring.

Nationwide case-finding has been implemented through the Epi-X system. The target audience of the case finding will include, but not be limited to, state and local health departments. They will be asked to report any potential cases to CDC. Information on each case will be collected using a data collection form that can be completed online or filled out and returned to CDC. Depending on the nature of each case, CDC may reach out to relevant healthcare facilities or healthcare staff for additional information and recommendation of any prevention measures.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

## **2. Purpose and Use of Information Collection**

The data collected from the investigation will be used to identify potential risk factors leading to *Serratia marcescens* infections among U.S. healthcare patients in order to prevent further adverse events. This request is to obtain OMB approval for collection of patient-level data from state and local health departments.

CDC cannot reasonably comply with the normal clearance procedures due to the public harm that is reasonably likely to result if routine processing of this request is required, specifically death due to infections in patients exposed to a contaminated healthcare product. Therefore CDC requests a 90-day emergency clearance to conduct national case-finding and data collection for similar patient events.

### **3. Use of Improved Information Technology and Burden Reduction**

Medical charts (electronic and paper) of case patients in multiple states will be abstracted onto paper forms by public health officials at state and local health departments. The data may be entered into an electronic database and used for future analysis. If available, information on cases identified through case finding may be submitted electronically to CDC via online secure submission form to CDC using the data collection form; however, no personal identifiable information will be included in such online communication.

We estimate that 30% of responses will be sent electronically. We do not expect any means of electronic transmission of patient data directly from a healthcare facility medical chart system.

### **4. Efforts to Identify Duplication and Use of Similar Information**

CDC is not aware of similar data regarding this particular type of event. CDC is communicating and coordinating with FDA colleagues who have queried their MedWatch systems.

### **5. Impact on Small Businesses or Other Small Entities**

The collection of information does not primarily involve small entities. However, for the small entities involved, the burdens imposed by CDC's information collection requirements have been reduced to the minimum necessary for CDC to meet its regulatory and public health responsibilities.

### **6. Consequences of Collecting the Information Less Frequently**

This is a one-time data collection. The information collected is critical to identify potential risk factors associated with *Serratia marcescens* infections among healthcare patients and help prevent additional events.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day *Federal Register* notice will be submitted to make the public aware of this investigation (Attachment 2).

B. The efforts to consult outside the agency are outlined below:

The Colorado Department of Public Health & Environment was the first agency to report the case-patients. CDC has been working with the following experts since March 2018:

Sarah Janelle, MPH, CIC

Healthcare-Associated Infections and Antimicrobial Resistance Epidemiologist

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A CDC team is working closely with the Colorado Department of Public Health and Environment and other state health departments to identify risk factors leading to those severe adverse events and prevent additional events.

CDC has also been working with colleagues at FDA on this issue since April 2018.

### **9. Explanation of Any Payment or Gift to Respondents**

No monetary incentives or gifts are provided to respondents.

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

The National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) reviewed this submission and determined that the Privacy Act does not apply.

Data will be collected anonymously to ensure the privacy of patients whose charts were reviewed.

CDC staff will follow procedures for assuring and maintaining privacy during all stages of data collection. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. This public health response was determined to be Not Human Subjects Research and does not require IRB approval.

#### *Privacy Impact Assessment Information*

In this activity, no identifiable information of patients and staff will be collected. However, we will collect contact information (name, email, phone number) of persons (such as local health department staff) who report cases to CDC via submission of the data collection tool (Attachment 3). The information will be used for follow-up of the cases.

Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems," last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994.

CDC will treat information in a secure manner and will not disclose, unless otherwise compelled by law. Forms will be kept in a locked file cabinet when not in use and only CDC staff is accessible to the

forms. Any electronic database that maintains such information will be kept in secure computers accessible to only CDC staff.

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

#### Institutional Review Board (IRB)

The protocols and tools used to conduct this information collection request have been reviewed and approved by NCEZID’s Human Subjects Advisor, who determined that this data collection does not meet the definition of research under 45 CFR 46.102(d). IRB review was not required (Attachment 4).

#### Justification for Sensitive Questions

In this activity, no sensitive questions will be asked.

### 12. Estimates of Annualized Burden Hours and Costs

The estimated burden to respondents is summarized in Table 12-A and Table 12-B below. This is an estimate based on receiving responses from 25 state health departments and 25 local health departments.

The chart abstraction form takes an average of two hours to complete. It’s estimated that 50 state or local health departments will each complete the form twice for a total estimated burden of 200 hours.

Table 12-A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
State and local health department staff	Records abstraction form for patients who suffered from <i>Serratia marcescens</i> infection	50	2	2	200
<b>Total</b>					200

There will be no anticipated costs to respondents other than time. Registered nurses are often the persons interviewed at hospitals. The 2017 U.S. median national hourly wage for registered nurses is \$33.65 (see [http://www.bls.gov/oes/current/oes\\_nat.htm#00-0000](http://www.bls.gov/oes/current/oes_nat.htm#00-0000)) and this was used to represent the hospital staff wages. This wage is assumed for general respondents because of the variety of types expected.

Table 12-B. Estimated Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
State and local health department staff	Records abstraction form for patients who suffered from <i>Serratia marcescens</i> infection	200	\$33.65	\$6,730
<b>Total</b>				\$6,730

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

None.

### 14. Annualized Cost to the Government

The estimated average annual cost to the federal government for the proposed information collection activities is \$26,329.20. This figure encompasses 50% FTE of two GS-12 employees for four weeks doing data collection, 50% of two GS-12 employees doing data analysis for two weeks, and ancillary information collection costs. The average hourly rate was obtained from the Office of Personnel Management's website (<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2016/general-schedule/>). The hourly rate for a GS-12 in metro Atlanta is \$36.92.

Estimated Annualized Cost to the Government per Activity and Total				
Activity	Time in hours required to perform activity	Number of employees performing activity	Average hourly wage of staff reviewing data	Total Estimated Yearly Cost
Data collection	160	2	\$36.92	\$5,907.20
Data analysis	80	2	\$36.92	\$2,953.60
<b>Total</b>				<b>\$8,860.80</b>

### 15. Explanation for Program Changes or Adjustments

This is a new information collection.

### 16. Plans for Tabulation and Publication and Project Time Schedule

Project Time Schedule	
Activity	Time Schedule
Data collection	1 day after OMB approval
Data analysis	1–2 months after OMB approval
Generation of report	6 months after OMB approval

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

The display of the OMB Expiration date is not inappropriate.

### 18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

### Attachments

1. Authorizing Legislation
2. 60-Day Federal Register Notice
3. Patient records abstraction tool



#### 4. Non-Research determination