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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-18ACN; Docket No. CDC-2018-0042]

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 Undetermined cause of Serratia marcescens infections — Multiple States, 2018. The goal of this investigation is to identify potential risk factors leading to an outbreak of Serratia marcescens infections among US healthcare patients. Data will be used to identify a cause of the infections and prevent additional events from occurring.

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-2018-0042 by any of the following methods:

- Federal eRulemaking Portal: 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, N.E., MS-D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 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; and
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.

5. Assess information collection costs.

Proposed Project

Undetermined cause of Serratia marcescens infections — Multiple States, 2018 – New – National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

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.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Healthcare staff	Case finding for data collection	25	2	25/50	100
Total					100

Jeffrey M. Zirger,

Acting Chief,

Information Collection Review Office,

Office of Scientific Integrity,

Office of the Associate Director for Science,

Office of the Director,

Centers for Disease Control and Prevention.

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