DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30341-3724

September 13, 2024

Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC

Subject: Request for Emergency Review and Clearance

Dear Mr. Mancini:

Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, Becton Dickinson BACTEC™ Blood Culture Media Bottles Shortage Impact Questionnaire be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and that this information is essential in the continued and uninterrupted operation of the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).

On July 10, 2024, The U.S. Food and Drug Administration (FDA) updated the Medical Device Shortages List to include BD BACTEC blood culture media bottles and issued a letter to Health Care Providers regarding the disruption in supply[1]. The supply disruption is expected to impact patient diagnosis, follow up patient management, bloodstream infection surveillance, and antimicrobial stewardship efforts. The FDA has recommended that health care facilities, laboratories, and health care providers develop strategies to prioritize the use of blood culture media bottles, based on clinical need, to maintain quality and safety of patient care. On July 23, 2024, the CDC issued a Health Alert Network Health Advisory to inform healthcare providers, laboratory professionals, healthcare facility administrators, and state, tribal, local, and territorial health departments of a critical shortage of Becton Dickinson (BD) BACTEC™ blood culture media bottles[2].

Blood cultures identify microorganism that cause infections and are critical for diagnosing patients with bloodstream infections and associated conditions including catheter-related bloodstream infections and sepsis. Blood cultures also assist health care providers in determining and guiding optimal therapy for treatment of these infections. Most blood cultures in the United States are performed using continuous-monitoring blood culture systems; the BD continuous-monitoring blood culture system is used in about half of all U.S. laboratories and is only compatible with BD BACTEC™ blood culture media bottles.

Federal laws and regulations require mandatory reporting of facility-specific adverse events, prevention practice adherence, and other public health data. NHSN is the nation's most widely used healthcare-associated infection (HAI) tracking system and provides facilities, health departments, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate HAIs, including blood stream infections (BSIs). The blood culture media bottle

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shortage data is needed to understand how reporting of HAIs is impacted, which informs stakeholder perception of other emerging HAI outcomes (e.g., patient mortality). Additionally, Centers for Medicare & Medicaid Services (CMS) quality reporting programs use HAI data reported to NHSN to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers, specifically bloodstream infection surveillance data. Facilities that fail to report quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. Many healthcare facilities in states without HAI reporting legislation also voluntarily submit HAI data to NHSN.

CDC consulted with CMS, Healthcare Infection Control Practices Advisory Committee (HICPAC), American Hospital Association (AHA), American Society for Microbiology (ASM), The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) about the development of the shortage impact questionnaire, and is fully committed to ensuring complete and accurate reporting of HAI data, which are critical for protecting patients and guiding national, state, and local prevention priorities. Data received from this collection will be shared with CMS. The interruptions in the supply of Becton Dickinson (BD) BACTEC™ blood culture media bottles will likely affect facility reporting of HAIs (bloodstream infection surveillance data) to NHSN and may ultimately affect facility payment from CMS.

CDC is preparing a 60-day Federal Register Notice to allow the public to comment on this information collection project. However, CDC NHSN cannot reasonably comply with the normal clearance process given the fact that this shortage may affect mandated CMS pay-for-performance quality reporting programs. This information collection request (ICR) includes a new data collection instrument and needs to go forward as an emergency request to assess the shortage's impact on facilities and bloodstream infection surveillance. Approval is requested for six months, with an expiration date of April 30, 2025.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business 9/27/2024.

Respectfully,

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Daniel B. Jernigan, MD MPH
Director, National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention

1. U.S. Food & Drug Administration. Disruptions in Availability of BD BACTEC Blood Culture Media Bottles https://www.fda.gov/medical-devices/letters-health-care-providers/disruptions-availability-bd-bactec-blood-culture-media-bottles-letter-health-care-providers. Accessed September 5, 2024.
2. Centers for Disease Control and Prevention. Disruptions in Availability of Becton Dickinson (BD) BACTEC™ Blood Culture Bottles. https://emergency.cdc.gov/han/2024/han00512.asp. Accessed September 5, 2024.