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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-19BCG; Docket No. CDC-2019-0053]

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 Core Elements of Antimicrobial Stewardship in Nursing Homes. The goal of the information collection is to assess the impact of an intervention on the knowledge, attitudes, practices, and perceived provider-level barriers to appropriate antibiotic prescribing in a sample of health care providers in nursing homes. The data will be used to monitor the effect of an intervention aimed at improving the antibiotic stewardship behaviors of prescribers in long-term care settings.

DATES: CDC must receive written comments on or before September 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0053 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 NE, 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 CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: 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

Core Elements of Antimicrobial Stewardship in Nursing Homes—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this survey is to follow-up on formative research (OMB Control Number 0920-1154), which assessed the knowledge, attitudes, practices and perceived provider-level barriers to appropriate antibiotic prescribing in a sample of health care providers in nursing homes. This survey was developed building upon foundational work previously completed. The questions were originally pre-tested among a select group (n=9) of prescribers recruited from the participating corporations to both obtain responses, as well as performing cognitive assessment to ensure clarity and robustness of content.

The preliminary findings suggested that the questions presented were clear and correctly understood and that the topics covered were meaningful. The inclusion of length of time in practice was specifically relevant as preliminary findings from the interviews, albeit limited, suggest that a prescriber's approach and attitudes surrounding antibiotic prescribing may be impacted by professional tenure. Specifically, respondents described that the longer a prescriber had been in practice, the more reluctant they were to modify their prescribing behaviors.

General findings consistently centered on the variability in nurse/provider communication. Themes of poor communication encompassed multiple elements. Key themes included: Poor structure of information sharing, the role of gatekeepers to the prescriber, insufficient or otherwise irrelevant detail, and an absence of therapy recommendation from the nurses. Additionally, respondents described the physical environment/geographic context that contributed to possible instances of over-prescribing: Limited availability of timely or rapid test laboratory results, sites with affiliated labs that are closed on the weekends (thus requiring a staff member to drive a sample multiple hours to the nearest hospital), limited antibiotic options in the facility's Emergency Kit (from which staff frequently draw when starting a prescription).

The current phase incorporates the findings from previous exploratory work and aims to address the quality of communication between the nurses and prescribers while also respecting the rational for initial antibiotic initiation. As the decision to initiate an antibiotic prescription is largely influenced by factors beyond the scope of this project, the current study targeted the role of the antibiotic follow-up to engage the prescriber post-prescription to reassess

the appropriateness of the initial prescription. Additional topics were identified as important to the respondents as they expressed support to include questions that cover individual perceptions of responsibility/autonomy, the importance of the role of family and other social pressures when deciding to make antibiotic decisions, and the process of following up with the resident post-prescription. The group of respondents were comprised of a semi-convenience sample, with efforts to target key administrative and practicing roles within the healthcare setting to

obtain a diverse and inclusive perspective.

Information will be used to provide descriptive analysis reports of the prescribing climate within long-term care settings. We will use these data as comparison to the initial survey deployment to characterize any change demonstrated within the current antimicrobial stewardship environment with an effort to identify key elements based on staff interactions, perceived challenges, and any identifiable gaps in knowledge. The specific elements within the survey will be used to identify common needs shared across

prescribers as areas for further training or intervention development (*e.g.*, identified barriers to education or training resources will result in a more robust education component to be included in future work). While this second survey is not intended to establish a direct causal relationship, it does aim to capture differences in a pre/post analysis style review without which, the initial survey would simply provide a snapshot of current levels of knowledge, attitudes, practices and perceived provider-level barriers to appropriate antibiotic prescribing.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Doctors	Core Elements of Antimicrobial Stewardship in Nursing Homes.	75	1	30/60	38
Nurse Practitioners	Core Elements of Antimicrobial Stewardship in Nursing Homes.	25	1	30/60	12
Total					50

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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[30Day-19-19ACB]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “The Drug Overdose Surveillance and Epidemiology (DOSE)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on April 2, 2019 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project.

The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW,

Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Drug Overdose Surveillance and Epidemiology (DOSE)—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The rapid increase in opioid overdose deaths since 2013, numerous severe fentanyl and fentanyl analog outbreaks occurring since 2015 across the United States, and the declaration of the opioid overdose epidemic as a national public health emergency on October 26, 2017 have highlighted the urgent need to rapidly establish and enhance timely surveillance of suspected drug, opioid, heroin, and stimulant overdoses. These data are critical to inform timely local, state, and regional response, especially to acute and/or widespread multi-state outbreaks.

This new data collection effort is an essential component toward reducing the opioid crisis, one of HHS Department's top priorities. DOSE data is critical to our ability to rapidly identify outbreaks and provide situational awareness of changes in emergency department (ED) visits involving suspected drug, opioid, heroin and stimulant overdoses at the local, state, and regional level. This will