

administered or dispensed. Additional persons who are qualified persons pursuant to section 319F-3(i)(8)(B) are the following: None.

VII. Additional Time Periods of Coverage After Expiration of Declaration (as Required by Section 319F-3(b)(3)(B) of the Act)

A. I have determined that, upon expiration of the applicable time period specified in Section III above, an additional twelve (12) months is a reasonable period to allow for the manufacturer to arrange for disposition of the Covered Countermeasure, including the return of such product to the manufacturer, and for covered persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasure, and the liability protection of section 319F-3(a) of the Act shall extend for that period.

B. The Federal Government shall purchase the entire production of Covered Countermeasures under the contracts specifically listed by contract number in section I for the stockpile under section 319F-2 of the Act, and shall be subject to the time-period extension of section 319F-3(b)(3)(C). Production under future contracts for the same vaccine will also be subject to the time-period extension of section 319F-3(b)(3)(C).

VIII. Amendments

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was published on January 26, 2007 and amended on November 30, 2007 to add H7 and H9 vaccines and on October 17, 2008 to add H2 and H6 vaccines. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F-2(b)(4) of the Act.

IX. Definitions

For the purposes of this declaration, “pre-pandemic phase” means the following stages, as defined in the National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (0) New Domestic Animal Outbreak in At-Risk Country; (1) Suspected Human Outbreak Overseas; (2) Confirmed Human Outbreak Overseas; and (3) Widespread Human Outbreaks in Multiple Locations Overseas. For the purposes of this declaration, “pandemic phase” means the following stages, as defined in the

National Strategy for Pandemic Influenza: Implementation Plan (Homeland Security Council, May 2006): (4) First Human Case in North America; and (5) Spread Throughout United States.

Dated: June 15, 2009.

Kathleen Sebelius,
Secretary.

Appendix

I. List of U.S. Government Contracts—Covered H5N1 Vaccine Contracts [January 26, 2007]

1. HHSN266200400031C
2. HHSN266200400032C
3. HHSN266200300039C
4. HHSN266200400045C
5. HHSN266200205459C
6. HHSN266200205460C
7. HHSN266200205461C
8. HHSN266200205462C
9. HHSN266200205463C
10. HHSN266200205464C
11. HHSN266200205465C
12. HHSN266199905357C
13. HHSN266200300068C
14. HHSN266200005413C
15. HHSO100200600021C (formerly 200200409981)
16. HHSO100200500004C
17. HHSO100200500005I
18. HHSO100200700026I
19. HHSO100200700027I
20. HHSO100200700028I
21. HHSO100200600010C
22. HHSO100200600011C
23. HHSO100200600012C
24. HHSO100200600013C
25. HHSO100200600014C
26. HHSO100200600022C (formerly 200200511758)
27. HHSO100200600023C (formerly 200200410431)
28. CRADA No. AI-0155 NIAID/MedImmune
29. HHSO100200700029C
30. HHSO100200700030C
31. HHSO100200700031C

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-09-09BX]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects.

Alternatively, to obtain a copy of the data collection plans and instrument, call 404-639-5960 and send comments to Maryam I. Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, NE., MS-D74, Atlanta, Georgia 30333; comments may also be sent by e-mail to omb@cdc.gov.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have a practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Clostridium difficile Infection (CDI) Surveillance—New—National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Steady increases in the rate and severity of *Clostridium difficile* infection (CDI) indicate a clear need to conduct longitudinal assessments of the impact of CDI in the United States. *C. difficile* is an anaerobic, spore-forming, gram positive bacillus that produces two pathogenic toxins: A and B. CDI ranges in severity from mild diarrhea to fulminant colitis and death. Transmission of *C. difficile* occurs primarily in healthcare facilities, where environmental contamination by *C. difficile* spores and exposure to antimicrobial drugs are common. No longer limited to healthcare environments, community-associated CDI is the focus of increasing attention. Recently, several cases of serious CDI have been reported in what have been considered low-risk populations, including healthy persons living in the community and peri-partum women.

For this proposed data collection, the surveillance population will consist of persons residing in the catchment area of the participating Emerging Infections Program (EIP) sites. This surveillance poses no more than minimal risk to the study participants as there will be no interventions or modifications to the care study participants receive. EIP surveillance personnel will perform active case finding from laboratory reports of stool specimens testing

positive for *C. difficile* toxin and abstract data on cases using a standardized case report form. For a subset of cases (e.g., community-associated *C. difficile* cases) sites will administer a health interview. Remnant stool specimens from cases testing positive for *C. difficile* toxin will be submitted to reference laboratories for culturing, and isolates will be sent to CDC for confirmation and molecular typing. Outcomes of this surveillance project will include the population-based incidence of community- and healthcare-associated CDI among participating EIP sites, characterization of *C. difficile* strains that are responsible

for CDI in the population under surveillance with a focus on strains from community-associated cases, a description of the epidemiology of community- and healthcare-associated CDI, and hypothesis-generation for future activities using EIP CDI surveillance infrastructure.

The proposed surveillance for CDI through the Emerging Infections Program will expand CDC capacity to monitor incidence of *C. difficile* in community and healthcare settings as well as to monitor and detect antimicrobial resistance. This activity supports the HHS Action Plan for elimination of healthcare-associated infections.

CDC estimates that a total of 7,650 CDI Surveillance Case Report Forms (CRFs) will be completed during a one-year study period on incident CDI cases within the EIP catchment area. Approximately 3,825 cases will require a completed CRF; the remaining 3,825 cases will only require a partially completed CRF. CDC estimates that 1,700 CDI Surveillance Health Interviews (HI) will be completed during a one-year study period. Surveillance Officers at the EIP sites will complete and submit the case report forms and health interviews. There are no costs to respondents.

ESTIMATES OF ANNUALIZED BURDEN

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
CDI Surveillance Case Report Form—Complete.	EIP Surveillance Officer	10	383	1	3,830
CDI Surveillance Case Report Form—Partial.	EIP Surveillance Officer	10	382	15/60	955
CDI Surveillance Health Interview	EIP Surveillance Officer	10	170	45/60	1,275
Total	6,060

Dated: June 17, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection

plans and draft instruments, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: HRSA/Bureau of Primary Health Care Capital Improvement Program Application Electronic Health Records (EHR) Readiness Checklist (OMB No. 0915-0325)—Extension

The American Recovery and Reinvestment Act (ARRA) provides \$1.5 billion in grants to support “construction, renovation and equipment”, and “the acquisition of health information technology systems, for health centers including health

center controlled networks receiving operating grants under section 330” of the Public Health Service (PHS) Act, as amended (42 U.S.C. 254b). HRSA is requesting extension of the approval of the Electronic Health Records (EHR) Readiness Checklist portion of the application where applicants must provide information to demonstrate readiness for electronic health records if they propose to use funds for electronic health record (EHR) related purchases. Of the \$1.5 billion, HRSA will award approximately \$850 million, through limited competition grants, for one-time Capital Improvement Program (CIP) grant funding in fiscal year (FY) 2009 to support existing section 330 funded health centers. Funding under this opportunity will address pressing capital improvement needs in health centers, such as construction, repair, renovation, and equipment purchases, including health information technology systems. Applicants must provide information using the EHR Readiness Checklist that demonstrates comprehensive planning and readiness for implementing EHRs.

The estimated annual burden is as follows: