

8. May Applications Be Faxed or Sent Electronically?

No. Applications transmitted by fax or through other electronic means will not be accepted regardless of date or time of submission or receipt.

9. Where Can Additional Copies of the Announcement and/or Forms Be Obtained?

The complete package, announcement and standard forms, may be obtained by calling *to be determined*.

Dated: June 9, 2003.

William F. Raub,

Acting Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-03-79]

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. To request more information on the

proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

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 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 automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: National Healthcare Safety Network (NHSN)—New— National Center for Infectious Disease (NCID), Centers for Disease Control and Prevention (CDC). OMB first approved the information collection now known as the "National Nosocomial Infections Surveillance (NNIS) System" (OMB No.0920-0012) in 1970; it approved the "National Surveillance System for Healthcare Workers(NaSH)" (OMB 0920-0417) in 1997, and the "Surveillance for Bloodstream and Vascular Access Infections in Outpatient Hemodialysis Centers" (OMB No. 0920-0442) in 1999. These three data collections have been

modified and are being merged to create the NHSN. The NHSN will evolve with the addition of modules and participating healthcare institutions from a wide spectrum of settings.

The NHSN is a knowledge system for accumulating, exchanging, and integrating relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and to promote healthcare safety. Specifically, the data will be used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare workers with similar risks. They will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks.

Healthcare institutions that participate in NHSN voluntarily report their data to the Division of Healthcare Quality Promotion in the National Center for Infectious Diseases at the Centers for Disease Control and Prevention through the National Electronic Disease Surveillance System that uses a web browser-based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. The cost to participating institutions is a computer capable of supporting an internet service provider (ISP) and access to an ISP. The table below shows the estimated annual burden in hours to collect and report data.

Title	Number of respondents	Number of responses/ respondent	Burden per response (in hrs.)	Total burden (hrs.)
NHSN Application/Annual Survey	350	1	1	350
Dialysis Application/Annual Survey	80	1	1	80
Patient Safety Monthly Reporting Plan	350	9	25/60	1,313
Patient Data	350	111	5/60	3,238
Surgical Site Infection (SSI)	200	27	25/60	2,250
Pneumonia (PNEU)	200	54	25/60	4,500
Primary Bloodstream Infection (BSI)	230	54	25/60	5,175
Urinary Tract Infection (UTI)	150	45	25/60	2,813
Dialysis Incident (DI)	80	90	12/60	1,440
Denominator for Procedure	200	540	5/60	9,000
Denominator for Specialty Care Area (SCA)	75	9	5	3,375
Denominator for Neonatal Intensive Care Unit (NICU)	100	9	4	3,600
Denominator for Intensive Care Unit (ICU)/Other locations (Not NICU or SCA)	245	18	5	22,050
Denominator for Outpatient	80	9	5/60	60
Antimicrobia 1 Use and Resistance (AUR)—Pharmacy	20	36	2	1,440
Healthcare Personnel Safety Reporting Plan	90	2	10/60	30
Healthcare Personnel Exposures to Blood/Body Fluids	90	42	1	3,780
Healthcare Personnel Post-exposure Prophylaxis	90	6	15/60	135
Healthcare Personnel Demographic Data	90	42	10/60	630
Healthcare Personnel Vaccination History	90	42	15/60	945
Healthcare Personnel Facility Survey	90	1	6	540
Healthcare Personnel Implementation of Engineering Controls	90	1	6	540
Healthcare Personnel Survey	30	1	10/60	5

Title	Number of respondents	Number of responses/ respondent	Burden per response (in hrs.)	Total burden (hrs.)
Total	67,289

Dated: June 12, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Food and Drug Administration

RIN 0920-AA03

Control of Communicable Diseases

AGENCIES: Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Department of Health and Human Services (HHS).

ACTION: Notice of embargo and prohibition on transportation or offering for transportation in interstate commerce, or sale, offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of certain rodents and Prairie dogs.

SUMMARY: Shipments of rodents (order *Rodentia*) from Africa capable of transmitting monkeypox virus in humans are being imported into the United States and further distributed. In the United States, Prairie dogs (*Cynomys sp.*) and certain rodents from Africa may further transmit the monkeypox virus in humans.

Because of the public health threat posed by the importation of rodents from Africa, CDC is implementing an immediate embargo on the importation of all rodents (order *Rodentia*) from Africa until further notice. In addition, as a public health measure, CDC and FDA are prohibiting, until further notice, the transportation or offering for transportation in interstate commerce, or the sale or offering for sale, or offering for any other type of commercial or public distribution, including release into the environment, of Prairie dogs and the following rodents from Africa: Tree squirrels (*Heliosciurus sp.*); Rope squirrels (*Funisciurus sp.*); Dormices (*Graphiurus sp.*); Gambian Giant Pouched Rats (*Cricetomys sp.*); Brush-tailed

porcupines (*Atherurus sp.*), Striped mice (*Hybomys sp.*).

This prohibition does not apply to individuals who transport listed animals to veterinarians or animal control officials or other entities pursuant to guidance or instructions issued by Federal, State, or local government authorities.

This action is being taken because at least six different species of potentially infected rodents have been implicated in the current outbreak of monkeypox virus in humans. Monkeypox virus was also subsequently transmitted from infected rodents to native Prairie dogs. Based on epidemiologic and scientific knowledge gathered to date, specific interstate restrictions on the species within these genera are required to contain further movement of implicated animals. A ban on the intrastate sale or offering for sale or offering for any other type of commercial or public distribution of the species within these genera is also necessary because of the potential impact on interstate disease spread. Furthermore, a ban on the importation of shipments of all rodents from Africa is necessary to mitigate the harm of further introductions of monkeypox virus into the United States.

DATES: This embargo and prohibition is effective on June 11, 2003, and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Thomas A. Demarcus, National Center for Infectious Diseases (E03), Centers for Disease Control and Prevention, 1600 Clifton Road, NE., Atlanta, GA 30333, 770-488-7100, or Gloria Dunnavan, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place (HFV-230), Rockville, MD 20855, 301-827-1168.

SUPPLEMENTARY INFORMATION:

I. Background

As of June 10, a total of 50 persons with suspected monkeypox had been reported from Wisconsin, Illinois, Indiana, and New Jersey. Monkeypox had been confirmed by laboratory tests in four persons. Seven of the people with suspected monkeypox had been hospitalized for their illness; there have been no deaths related to the outbreak. The number of cases and States

involved in the outbreak will likely change as the investigation continues.

Onset of illness among patients began in early May. All patients reported direct or close contact with Prairie dogs, most of which were sick. In May, the Prairie dogs were sold by a Milwaukee animal distributor to two pet shops in the Milwaukee area and during a pet "swap meet" (pets for sale or exchange) in northern Wisconsin. The Milwaukee animal distributor had obtained Prairie dogs and a Gambian giant rat that was ill at the time from a northern Illinois animal distributor. On the basis of preliminary findings from the trace-back investigation of the Prairie dogs and the Gambian giant rat, it appears that the source of the infection was a shipment of rodents from Africa, which included six distinct species of rodents. It appears that the primary route of transmission may be from infected rodents from Africa to native Prairie dogs and then to humans as a result of close contact.

II. Public Health Risks

Monkeypox is a rare zoonotic viral disease that occurs primarily in the rain forest countries of central and west Africa. Studies have shown that rodents from Africa are capable of transmitting monkeypox virus in humans. In humans, the illness produces a vesicular and pustular rash similar to that of smallpox. Limited person-to-person spread of infection has been reported in disease-endemic areas in Africa; the incubation period is about 12 days. Case-fatality ratios in Africa have ranged from 1 percent to 10 percent. It is likely the virus entered the United States via imported rodent species from Africa. Further transmission of the virus likely occurred in the storage and handling of these imported rodents during sale and distribution within the United States. This resulted in secondary transmission to domestic Prairie dogs housed in the same animal-holding facility or pet shop.

III. Immediate Action

Introduction of exotic species, such as rodents from Africa, poses a serious public health threat because of the potential of human monkeypox virus infection. Transportation in interstate commerce or sale or any other type of commercial or public distribution, including release into the environment, of species of rodents linked to the initial