

Dated: April 17, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-0821]

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 404-639-7570 and send comments to Ron Otten, at CDC, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an email 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 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. Written comments should be received within 60 days of this notice.

Proposed Project

Quarantine Station Illness and Death Investigation Forms—Airline, Maritime, Land/Border Crossing Illness and Death Investigation Forms—Revision—National Center for Zoonotic and Emerging Infectious Diseases (NCEZID) (0920-0821, expires 9/30/2012), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is requesting a revision to an existing data collection of patient-level clinical, epidemiologic, and demographic data from ill travelers and their possible contacts in order to fulfill its regulatory responsibility to prevent the importation of communicable diseases from foreign countries (42 CFR part 71) and interstate control of communicable diseases in humans (42 CFR part 70).

Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) authorizes the Secretary of Health and Human Services to make and enforce regulations necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the United States. The regulations that implement this law, 42 CFR parts 70 and 71, authorize quarantine officers and other personnel to inspect and undertake necessary control measures with respect to conveyances (e.g., airplanes, cruise ships, trucks, etc.), persons, and shipments of animals and etiologic agents in order to protect the public's health. The regulations also require conveyances to immediately report an "ill person" or any death on board to the Quarantine Station prior to arrival in the United States. An "ill person" is defined in statute by:

- Fever (≥ 100 °F or 38 °C) persisting ≥ 48 hours
- Fever (≥ 100 °F or 38 °C) AND rash, glandular swelling, or jaundice
- Diarrhea (≥ 3 stools in 24 hours or greater than normal amount)

The 2003 Severe Acute Respiratory Syndrome (SARS) situation and concern about pandemic influenza and other communicable diseases have prompted CDC Quarantine Stations to recommend that all illnesses be reported prior to arrival.

CDC Quarantine Stations are currently located at 20 international U.S. Ports of Entry. When a suspected illness is reported to the Quarantine Station, officers promptly respond to this report by meeting the incoming conveyance in person (when possible), collecting information and evaluating the patient(s), and determining whether an ill person can safely be admitted into the U.S. If Quarantine Station staff is unable to meet the conveyance, the crew or medical staff of the conveyance is trained to complete the required documentation and forward it (using a secure system) to the Quarantine Station for review and follow-up.

To perform these tasks in a streamlined manner and ensure that all relevant information is collected in the

most efficient and timely manner possible, Quarantine Stations use a number of forms—the Air Travel Illness or Death Investigation Form, Maritime Conveyance Illness or Death Investigation Form, and the Land Travel Illness or Death Investigation Form—to collect data on passengers with suspected illness and other travelers/crew who may have been exposed to an illness. These forms are also used to respond to a report of a death aboard a conveyance.

The purpose of all three forms is the same: to collect information that helps quarantine officials detect and respond to potential public health communicable disease threats. All three forms collect the following categories of information: Demographics and mode of transportation, clinical and medical history, and any other relevant facts (e.g., travel history, traveling companions, etc.). As part of this documentation, quarantine public health officers look for specific signs and symptoms common to the nine quarantinable diseases (Pandemic influenza; SARS; Cholera; Plague; Diphtheria; Infectious Tuberculosis; Smallpox; Yellow fever; and Viral Hemorrhagic Fevers), as well as most communicable diseases in general. These signs and symptoms include fever, difficulty breathing, shortness of breath, cough, diarrhea, jaundice, or signs of a neurological infection. The forms also collect data specific to the traveler's conveyance.

These data are used by Quarantine Stations to make decisions about a passenger's suspected illness as well as its communicability. This in turn enables Quarantine Station staff to assist conveyances in the public health management of passengers and crew.

The estimated total burden on the public, included in the chart below, can vary a great deal depending on the severity of the illness being reported, the number of contacts, the number of follow-up inquiries required, and who is recording the information (e.g., Quarantine Station staff versus the conveyance medical authority). In all cases, Quarantine Stations have implemented practices and procedures that balance the health and safety of the American public against the public's desire for minimal interference with their travel and trade. Whenever possible, Quarantine Station staff obtain information from other documentation (e.g., manifest order, other airline documents) to reduce the amount of the public burden.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Form	Number of respondents (2009, incl. H1N1)	Number of responses per respondent	Average burden per response (in minutes)	Total burden hours
Airline Travel Illness or Death Investigation Form	1626	1	5/60	136
Maritime Conveyance Illness or Death Investigation Form	1873	1	7/60	219
Land Travel Illness or Death Investigation Form	259	1	5/60	22
Total	3,758	377

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Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Enhancing Substance Abuse Treatment Services To Address Hepatitis Infection Among Intravenous Drug Users Hepatitis Testing and Vaccine Tracking Form (OMB No. 0930-0300)—Extension

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center Substance Abuse Treatment (CSAT), is responsible for the Hepatitis Testing and Vaccine Tracking Form for the prevention of Viral Hepatitis in patients in designated Opioid Treatment Programs (OTPs). There are no changes to the form or added burden.

This form allows SAMHSA/CSAT to collect essential Clinical information that will be used for quality assurance, quality performance and product monitoring on approximately 264 Rapid Hepatitis C Test kits and 10,628 doses of hepatitis vaccine (Twinrix, HAV, or HBV). The above kits and vaccines will be provided to designated OTPs serving the minority population in their communities. The information collected on the Form solicits and reflect the following information:

- Demographics (age, gender, ethnicity) of designated OTP site
- History (Screening) of Hepatitis C exposure
- Results of Rapid Hepatitis C Testing (Kit) and Follow-up information
- Service Provided (type of vaccine given) Divalent vaccine (Twinrix-combination HAV and HBV) or Monovalent vaccine (HAV and/or HBV)
- Substance Abuse Treatment Outcomes (Information regarding the beginning, continuing or completion of vaccination series)
- Type of Referral Services Indicated (i.e., Gastroenterology, TB; Mental Health, Counseling, Reproductive/Prenatal, etc.)

This program is authorized under Section 509 of the Public Health Service (PHS) Act [42 U.S.C. 290bb-2].

The form increases the screening and reporting of viral hepatitis in high risk minorities in OTPs. The information collected allows SAMHSA to address the increased morbidity and mortality of hepatitis in minorities being treated for drug addiction.

The SAMHSA/CSAT Hepatitis Testing and Vaccine Tracking Form supports quality of care, provide minimum but adequate clinical and product monitoring, and provide appropriate safeguards against fraud, waste and abuse of Federal funds.

The table below reflects the annualized hourly burden.

Number of respondents screened	Responses/ respondent	Burden hours	Total burden hours
50,000	1	0.05	2,500

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 8-1099, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at summer.king@samhsa.hhs.gov. Written comments must be received

before 60 days after the publication in the **Federal Register**.

Summer King,

Statistician.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG-2012-0274]

Information Collection Requests to Office of Management and Budget

AGENCY: Coast Guard, DHS.