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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-13-0307]

Proposed Data Collections Submitted for

Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

The Gonococcal Isolate Surveillance Project (GISP), OMB No.0920-0307 exp. 12/31/2013) – Revision – National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this request is to obtain Office of Budget

and Management (OMB) approval to revise the data collection for the Gonococcal Isolate Surveillance Project (GISP)(OMB No.0920-0307, expires 12/31/2013). CDC seeks a three-year approval to conduct the GISP project. Revisions to this ICR consist of removing 4 variables from Form 1: Demographic/Clinical Data. The four variables to be removed are: (1) total monthly number of gonococcal infections; (2) date of birth of the patient; (3) zip code of the patient; and (4) reason for visit. The variables to be removed have not proven useful at the federal level and removal of the variables will not increase or decrease the burden. The objectives of GISP are: (1) to monitor trends in antimicrobial susceptibility of strains of *Neisseria gonorrhoeae* in the United States and (2) to characterize resistant isolates. Surveillance of *N. gonorrhoeae* antimicrobial resistance is important because: (1) nearly all gonococcal infections are treated empirically and susceptibility testing data are not routinely available in clinical practice; (2) *N. gonorrhoeae* has consistently demonstrated the ability to develop resistance to the antimicrobials used for treatment; (3) effective treatment of gonorrhea is a critical component of gonorrhea control and prevention, and (4) untreated or inadequately treated gonorrhea can cause serious reproductive health complications. GISP is the only source in the United States of critical national, regional, and site-specific gonococcal antimicrobial resistance

data. GISP provides information to support informed and scientifically-based treatment recommendations.

GISP was established in 1986 as a voluntary surveillance project and now involves 5 regional laboratories and 30 publicly funded sexually transmitted disease (STD) clinics around the country. The STD clinics submit up to 25 gonococcal specimens (or isolates) per month to the regional laboratories, which measure susceptibility of the isolates to multiple antimicrobial drugs. Limited demographic and clinical information corresponding to the isolates (and that do not allow identification of the patient) are submitted directly by the clinics to CDC.

During 1986-2012, GISP has demonstrated the ability to effectively achieve its objectives. The emergence of resistance in the United States to penicillin, tetracyclines, and fluoroquinolones among *N. gonorrhoeae* isolates was identified through GISP. Increased prevalence of fluoroquinolone-resistant *N. gonorrhoeae* (QRNG), as documented by GISP data, prompted CDC to update treatment recommendations for gonorrhea in CDC's Sexually Transmitted Diseases Treatment Guidelines, 2006 and to release an MMWR article stating that CDC no longer recommended fluoroquinolones for treatment of gonococcal infections. Recently, GISP isolates demonstrated increasing minimum inhibitory concentrations of cefixime, which can be an early

warning of impending resistance. This worrisome trend prompted CDC to again update treatment recommendations and no longer recommend the use of cefixime as first-line treatment for gonococcal infections.

Under the GISP protocol, each of the 30 clinics submit an average of 20 isolates per clinic per month (i.e., 240 times per year) recorded on Form 1: Demographic/Clinical Data. The estimated time for clinical personnel to abstract data for Form 1: Demographic/Clinical Data is 11 minutes per response.

Each of the five Regional laboratories receives and processes approximately 20 isolates from each referring clinic per month (i.e., 121 isolates per regional laboratory per month [based on 2011 specimen volume]) using Form 2: Antimicrobial Susceptibility Testing. For Form 2: Antimicrobial Susceptibility Testing, the annual frequency of responses per respondent is 1,452 (121 isolates x 12 months). Based on previous laboratory experience, the estimated burden of completing Form 2 for each participating laboratory is 1 hour per response, which includes the time required for laboratory processing of the patient's isolate, gathering and maintaining the data needed, and completing and reviewing the collection of information. For Form 3: Control Strain Susceptibility Testing, a "response" is defined as the processing and recording of Regional laboratory data for a set of seven control strains. It takes approximately

12 minutes to process and record the Regional laboratory data on Form 3 for one set of seven control strains, of which there are 4 sets. The number of responses per respondent is 48 (4 sets x 12 months). There are no additional costs to respondents. The total estimated annual burden hours are 8,628.

Estimate of Annualized Burden Hours

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Avg. Burden per Response (in hours) |
|---|---|---|---|---|
| Clinic | Demographic Clinical Data Form 1 | 30 | 240 | 11/60 |
| Laboratory | Antimicrobial Susceptibility Testing Form 2 | 5 | 1,452 | 1 |
| | Control Strain Susceptibility Testing Form 3 | 5 | 48 | 12/60 |

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