

collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

**Prevent Hepatitis Transmission Among Persons Who Inject Drugs—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC)**

*Background and Brief Description*

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States; approximately 3 million persons are chronically infected. Identifying and reaching persons at risk for HCV infection is critical to prevent transmission and treat and cure if infected. CDC monitors the national incidence of acute hepatitis C through passive surveillance of acute, symptomatic cases of laboratory confirmed hepatitis C cases. Since 2006, surveillance data have shown a trend toward reemergence of HCV infection mainly among young persons who inject drugs (PWID) in nonurban counties. Of the cases reported in 2013 with information on risk factors 62% indicated injection drug use as the

primary risk for acute hepatitis C. The prevention of HCV infection among PWIDs requires an integrated approach including harm reduction interventions, substance abuse treatment, prevention of other blood borne infections, and care and treatment of HCV infection.

The purpose of the proposed study is to address the high prevalence of HCV infection by developing and implementing an integrated approach for detection, prevention, care and treatment of infection among persons aged 18–30 years who reside in non-urban counties. Awardees will develop and implement a comprehensive strategy to enroll young non-urban PWID, collect epidemiological information, test for HCV infection and provide linkage to primary care services, prevention interventions, and treatment for substance abuse and HCV infection. In addition to providing HCV testing, participants will be offered testing for the presence of co-infections with hepatitis B virus (HBV) and HIV. Rates of HCV infection or re-infection will be evaluated through follow-up blood tests. Furthermore, adherence to prevention services and retention in care will be assessed through follow up interviews.

The project will recruit an estimated total of 1,500 young PWIDs to enroll 1,000. The participants will be recruited from settings where young PWIDs obtain access to care and treatment services. Recruitment will be direct and in-person by partnering with local harm reduction sites. Recruiters will enroll subjects across recruitment sites

primarily through drug treatment programs and syringe exchange programs, as well as persons referred to these sites as a result of referral from other programs and respondent driven sampling. Those who consent to participate will be administered an eligibility interview questionnaire by trained field staff. If found eligible, the participant will take an interviewer-administered survey that includes information on initiation of drug use, injection practices, HCV and HIV infection status, access to prevention and medical care, desire to receive and barriers to receiving HCV treatment, and missed opportunities for hepatitis prevention. Participants will receive counselling regarding adherence to medical and/or drug treatment services and prevention services. Participants will be interviewed for a maximum of 5 times within any 12-month interval during the course of the study: Consent and interview at enrollment/baseline for an estimated 60 minutes, and 30-minute follow-up interviews every 3 months thereafter. Participants who are recruited early in the study have more follow-up interviews than those who are recruited in the later part of the study during the 3-year project. However, recruitment will be spread over 2 years and on average, the duration of follow-up is estimated to be one year.

Participation in interviews and responses to all study questions are totally voluntary and there is no cost to respondents other than their time. The maximum burden is 3,375 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Young PWIDs .....	Screener .....	1500	1	15/60	375
Eligible young PWIDs .....	Initial Survey .....	1000	1	60/60	1000
Eligible young PWIDs .....	Follow-up survey .....	1000	4	30/60	2000
<b>Total .....</b>	.....	.....	.....	.....	<b>3375</b>

**Maryam I. Daneshvar,**  
*Deputy Director, Office of Scientific Integrity,  
 Office of the Associate Director for Science,  
 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–15–0666; Docket No. CDC–2015–0048]**

**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 efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on the National Healthcare Safety Network (NHSN). NHSN is a

system designed to accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety.

**DATES:** Written comments must be received on or before August 31, 2015.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2015-0048 by any of the following methods:

- *Federal eRulemaking Portal:*

Regulation.gov. Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, 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. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

**Please note:** All public comment should be submitted 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 the 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 OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

*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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

**Proposed Project**

National Healthcare Safety Network (NHSN)—Revision—National Center for Emerging and Zoonotic Infection Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The National Healthcare Safety Network (NHSN) is a system designed to

accumulate, exchange, and integrate relevant information and resources among private and public stakeholders to support local and national efforts to protect patients and promote healthcare safety. Specifically, the data is 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. The data will be used to detect changes in the epidemiology of adverse events resulting from new and current medical therapies and changing risks. The NHSN currently consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility (LTCF), and Dialysis. The Outpatient Procedure Component is on track to be released in NHSN in 2016/2017. The development of this component has been previously delayed to obtain additional user feedback and support from outside partners.

Changes were made to seven facility surveys. Based on user feedback and internal reviews of the annual facility surveys it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys. The surveys are being increasingly used to help intelligently interpret the other data elements reported into NHSN. Currently the surveys are used to appropriately risk adjust the numerator and denominator data entered into NHSN while also guiding decisions on future division priorities for prevention.

Additionally, minor revisions have been made to 27 forms within the package to clarify and/or update surveillance definitions. Two forms are being removed as those forms will no longer be added to the NHSN system. The previously approved NHSN package included 54 individual collection forms; the current revision request removes two forms for a total of 52 forms. The reporting burden will increase by 583,825 hours, for a total of 4,861,542 hours.

**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)
Registered Nurse (Infection Preventionist).	NHSN Registration Form .....	2,000	1	5/60	167
Registered Nurse (Infection Preventionist).	Facility Contact Information .....	2,000	1	10/60	333
Registered Nurse (Infection Preventionist).	Patient Safety Component—Annual Hospital Survey.	5,000	1	50/60	4,167

## ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Registered Nurse (Infection Preventionist).	Group Contact Information .....	1,000	1	5/60	83
Registered Nurse (Infection Preventionist).	Patient Safety Monthly Reporting Plan.	6,000	12	15/60	18,000
Registered Nurse (Infection Preventionist).	Primary Bloodstream Infection (BSI)	6,000	44	30/60	132,000
Registered Nurse (Infection Preventionist).	Pneumonia (PNEU) .....	6,000	72	30/60	216,000
Registered Nurse (Infection Preventionist).	Ventilator-Associated Event .....	6,000	144	25/60	360,000
Registered Nurse (Infection Preventionist).	Urinary Tract Infection (UTI) .....	6,000	40	20/60	80,000
Staff RN .....	Denominators for Neonatal Intensive Care Unit (NICU).	6,000	9	3	162,000
Staff RN .....	Denominators for Specialty Care Area (SCA)/Oncology (ONC).	6,000	9	5	270,000
Staff RN .....	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	6,000	60	5	1,800,000
Registered Nurse (Infection Preventionist).	Surgical Site Infection (SSI) .....	6,000	36	35/60	126,000
Staff RN .....	Denominator for Procedure .....	6,000	540	5/60	270,000
Laboratory Technician .....	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables.	6,000	12	5/60	6,000
Pharmacy Technician .....	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables.	6,000	12	5/60	6,000
Registered Nurse (Infection Preventionist).	Central Line Insertion Practices Adherence Monitoring.	1,000	100	25/60	41,667
Registered Nurse (Infection Preventionist).	MDRO or CDI Infection Form .....	6,000	72	30/60	216,000
Registered Nurse (Infection Preventionist).	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	6,000	24	15/60	36,000
Registered Nurse (Infection Preventionist).	Laboratory-identified MDRO or CDI Event.	6,000	240	30/60	720,000
Registered Nurse (Infection Preventionist).	Long-Term Care Facility Component—Annual Facility Survey.	250	1	1	250
Registered Nurse (Infection Preventionist).	Laboratory-identified MDRO or CDI Event for LTCF.	250	8	15/60	500
Registered Nurse (Infection Preventionist).	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	250	12	5/60	250
Registered Nurse (Infection Preventionist).	Urinary Tract Infection (UTI) for LTCF.	250	9	30/60	1,125
Registered Nurse (Infection Preventionist).	Monthly Reporting Plan for LTCF ....	250	12	5/60	250
Registered Nurse (Infection Preventionist).	Denominators for LTCF Locations ...	250	12	3.25	9,750
Registered Nurse (Infection Preventionist).	Prevention Process Measures Monthly Monitoring for LTCF.	250	12	5/60	250
Registered Nurse (Infection Preventionist).	LTAC Annual Survey .....	400	1	50/60	333
Registered Nurse (Infection Preventionist).	Rehab Annual Survey .....	1,000	1	50/60	833
Occupational Health RN/Specialist ...	Healthcare Personnel Safety Component Annual Facility Survey.	50	1	8	400
Occupational Health RN/Specialist ...	Healthcare Personnel Safety Monthly Reporting Plan.	17,000	1	5/60	1,417
Occupational Health RN/Specialist ...	Healthcare Worker Demographic Data.	50	200	20/60	3,333
Occupational Health RN/Specialist ...	Exposure to Blood/Body Fluids .....	50	50	1	2,500
Occupational Health RN/Specialist ...	Healthcare Worker Prophylaxis/Treatment.	50	30	15/60	375
Laboratory Technician .....	Follow-Up Laboratory Testing .....	50	50	15/60	625
Occupational Health RN/Specialist ...	Healthcare Worker Prophylaxis/Treatment-Influenza.	50	50	10/60	417

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Annual Survey.	500	1	2	1,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Monthly Reporting Plan.	500	12	1/60	100
Medical/Clinical Laboratory Technologist.	Hemovigilance Module Monthly Reporting Denominators.	500	12	1	6,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Adverse Reaction ...	500	48	15/60	6,000
Medical/Clinical Laboratory Technologist.	Hemovigilance Incident .....	500	10	10/60	833
Staff RN .....	Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC).	5,000	1	5/60	417
Staff RN .....	Outpatient Procedure Component—Monthly Reporting Plan.	5,000	12	15/60	15,000
Staff RN .....	Outpatient Procedure Component Event.	5,000	25	40/60	83,333
Staff RN .....	Outpatient Procedure Component—Monthly Denominators and Summary.	5,000	12	40/60	40,000
Registered Nurse (Infection Preventionist).	Outpatient Dialysis Center Practices Survey.	6,500	1	2.0	13,000
Staff RN .....	Dialysis Monthly Reporting Plan .....	6,500	12	5/60	6,500
Staff RN .....	Dialysis Event .....	6,500	60	25/60	162,500
Staff RN .....	Denominators for Dialysis Event Surveillance.	6,500	12	10/60	13,000
Staff RN .....	Prevention Process Measures Monthly Monitoring for Dialysis.	1,500	12	1.25	22,500
Staff RN .....	Dialysis Patient Influenza Vaccination.	325	75	10/60	4,063
Staff RN .....	Dialysis Patient Influenza Vaccination Denominator.	325	5	10/60	271
Total .....	.....	.....	.....	.....	4,861,542

**Maryam I. Daneshvar,**  
*Deputy Director, Office of Scientific Integrity,  
 Office of the Associate Director for Science,  
 Office of the Director, Centers for Disease  
 Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

**Centers for Medicare and Medicaid Services**

**Notice of Hearing: Reconsideration of Disapproval Texas Medicaid State Plan Amendment (SPA) 14-25**

**AGENCY:** Centers for Medicare and Medicaid Services (CMS), HHS.

**ACTION:** Notice of Hearing: Reconsideration of Disapproval.

**SUMMARY:** This notice announces an administrative hearing to be held on August 6, 2015, at the Department of Health and Human Services, Centers for Medicare and Medicaid Services, Division of Medicaid & Children's

Health, Dallas Regional Office, 1301 Young Street, Room 714, Dallas, TX 75202, to reconsider CMS' decision to disapprove Texas' Medicaid SPA 14-25. *Closing Date:* Requests to participate in the hearing as a party must be received by the presiding officer by July 15, 2015.

**FOR FURTHER INFORMATION CONTACT:** Benjamin R. Cohen, Presiding Officer, CMS, 2520 Lord Baltimore Drive, Suite L, Baltimore, Maryland 21244; Telephone: (410) 786-3169.

**SUPPLEMENTARY INFORMATION:** This notice announces an administrative hearing to reconsider CMS' decision to disapprove Texas' Medicaid SPA 14-25, which was submitted to the Centers for Medicare and Medicaid Services (CMS) on August 26, 2014 and disapproved on April 7, 2015. In part, this SPA requested CMS approval to revise the methodology for calculating the hospital-specific limit for the Disproportionate Share Hospital (DSH) program. Specifically, SPA 14-25 proposed to exclude from the calculation, the portion of a Medicare payment for an individual who is

dually-eligible for Medicare and Medicaid that exceeds the Medicaid allowable cost for the service provided to the recipient. This exclusion would permit the state to make Medicaid DSH payments that are above and beyond hospitals' reported uncompensated costs of providing services to Medicaid and uninsured individuals.

The issue to be considered at the hearing is:

- Whether Texas SPA 14-25 is inconsistent with Medicaid DSH requirements of sections 1902(a)(13)(A)(iv) and 1923 of the Social Security Act (Act) because it would provide for payment to disproportionate share hospitals of amounts that exceed the hospital's uncompensated costs which cannot be considered consistent with DSH requirements pursuant to the hospital-specific limit under section 1923(g)(1) of the Act.

Section 1116 of the Act and federal regulations at 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a state plan or plan amendment. CMS is required to publish a copy of the notice