• The presence of a party on the UL in a transaction is a "red flag" that should be resolved before proceeding with the transaction.[27]

• In accordance with the EAR, if an order involves an export, both the provider and customer are required to maintain documentary evidence of the transaction and are prohibited from misrepresenting or concealing material facts in licensing processes and all export control documents.[23]

In order to avoid violating U.S. laws and regulations, providers are encouraged to check the international customer against the most recent versions of these lists of proscribed entities before filling each order.

The U.S. Government recommends that providers utilize a "Best Match" approach to identify sequences unique to pathogens, toxins, and genetic elements on the Commerce Control List for international orders, as well as identifying sequences unique to Select Agent and Toxins.

Contacting the U.S. Government

In cases where *follow-up screening* cannot resolve concerns raised by either *customer screening or sequence screening, or when providers are otherwise unsure about whether to fill an order,* the U.S. Government recommends that providers contact relevant agencies as described in Section VII.

Customer and Sequence Screening Software and Expertise

Providers should be aware that commercially available customer screening software packages may not necessarily address all aspects of *customer screening* recommended by the U.S. Government.

The U.S. Government recommends that:

• Providers select a sequence screening software tool that utilizes a local sequence alignment technique.

• Providers have the necessary expertise in-house to perform the sequence screenings, analyze the results, and conduct the appropriate follow-up research to evaluate the significance of dubious sequence matches.

Records Retention

The U.S. Government recommends that providers:

• Retain records of customer orders for at least eight years based on the statute of limitations set forth by U.S. Code of Federal Crimes and Procedures, Title 18 Section 3286.[28]

• Archive the following information: customer information (point-of-contact name, organization, address, and phone number), order sequence information (nucleotide sequences ordered, vector used), and order information (date placed and shipped, shipping address, and receiver name).

• Develop, maintain, and document protocols to determine if a sequence "hit" qualifies as a true "sequence of concern;" protocols that are no longer current should be maintained for at least eight years.

• Keep screening records of all "hits" for at least eight years, even if the order was deemed acceptable.

• Develop, maintain, and document their sequence screening protocols within company records; protocols that are no longer current should be maintained for at least eight years.

• Retain records of any *follow-up screening,* even if the order was ultimately filled, for at least eight years.

Dated: October 6, 2010.

Kathleen Sebelius,

Secretary, U.S. Department of Health and Human Services.

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BILLING CODE 4150–37–P

[27] The Unverified List is found on the Web site *http://www.bis.doc.gov/enforcement/unverifiedlist/unverified_parties.html.* It is updated periodically.

[28] Section 3286 specifies that no person shall be prosecuted, tried, or punished for any noncapital offense involving certain violations unless the indictment is found or the information is instituted within 8 years after the offense was committed. This statute of limitations applies to Title 18 Section 175(b) (possession of biological agents with no reasonable justification).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day–10–0666]

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 Carol E. Walker, Acting 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 will 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 clarify 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

National Healthcare Safety Network (NHSN) (OMB No. 0920–0666 exp. 3/31/2012)—Revision—National Center for Emerging and Zoonotic Infectious 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 to 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 consists of four components: Patient Safety, Healthcare Personnel Safety, Biovigilance, and eSurveillance. In general, the data reported under the Patient Safety Component protocols are used to (1) determine the magnitude of the healthcare-associated adverse events under study, trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices, and (2) to detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data will be used to describe the epidemiology of antimicrobial use and resistance and to understand the relationship of antimicrobial therapy to this growing problem. Under the Healthcare Personnel Safety Component protocols, data on events—both positive and adverse—are used to determine (1) the magnitude of adverse events in

healthcare personnel and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are used to provide national estimates of adverse reactions and incidents.

This revision submission includes an amended Assurance of Confidentiality, which required an update of the Assurance of Confidentiality language on all forms included in the NHSN surveillance system. The scope of NHSN dialysis surveillance is being expanded to include all outpatient dialysis centers so that the existing Dialysis Annual Survey can be used to facilitate prevention objectives set forth in the HHS HAI tier 2 Action Plan and to assess national practices in all Medicare-certified dialysis centers if CMS re-establishes this survey method (as expected). The Patient Safety (PS) Component is being expanded to include long-term care facilities to facilitate HAI surveillance in this setting, for which no standardized reporting methodology or mechanism currently exists. Four new forms are proposed for this purpose. A new form is proposed to be added to the Healthcare Personnel Safety (HPS) Component to facilitate summary reporting of influenza vaccination in healthcare workers, which is anticipated to be required by CMS in the near future. In addition to this new form, the scope of the HPS Annual Facility Survey is being expanded to include all acute care facilities that would enroll if CMS does implement this requirement. The NHSN Antimicrobial Use and Resistance module is transitioning from manual web entry to electronic data upload only, which results in a significant decrease to the reporting burden for this package. Eight forms that are no longer necessary are being removed from this information data request. Finally, there are many updates, clarifications, and data collection revisions proposed in this submission.

The previously approved NHSN package included 54 individual data collection forms; the current revision request includes five new forms and the removal of eight forms from the package. If all proposed revisions are approved, the reporting burden will decrease by 1,258,119 hours, for a total estimated burden of 3,914,125 hours.

Healthcare institutions that participate in NHSN voluntarily report their data to CDC using a web browser based technology for data entry and data management. Data are collected by trained surveillance personnel using written standardized protocols. Participating institutions must have a computer capable of supporting an Internet service provider (ISP) and access to an ISP. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Form number and name	Respondents	Number of respondents	Responses per respondent	Burden per response (in hours)	Total annual burden (in hours)
57.100: NHSN Registration Form	Registered Nurse (Infection Preventionist).	6,000	1	5/60	500
57.101: Facility Contact Information	Registered Nurse (Infection Preventionist).	6,000	1	10/60	1,000
57.103: Patient Safety Component—Annual Facility Survey.	Registered Nurse (Infection Preventionist).	6,000	1	40/60	4,000
57.104: Patient Safety Component—Outpatient Dialysis Center Practices Survey.	Registered Nurse (Infection Preventionist).	5,500	1	1	5,500
57.105: Group Contact Information	Registered Nurse (Infection Preventionist).	6,000	1	5/60	500
57.106: Patient Safety Monthly Reporting Plan	Registered Nurse (Infection Preventionist).	6,000	9	35/60	31,500
57.108: Primary Bloodstream Infection (BSI)	Registered Nurse (Infection Preventionist).	6,000	36	32/60	115,200
57.109: Dialysis Event	Staff RN	500	75	15/60	9,375
57.114: Urinary Tract Infection (UTI)	Registered Nurse (Infection Preventionist).	6,000	27	32/60	86,400
57.116: Denominators for Neonatal Intensive Care Unit (NICU).	Staff RN	6,000	9	4	216,000
57.117: Denominators for Specialty Care Area (SCA).	Staff RN	6,000	9	5	270,000
57.118: Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA).	Staff RN	6,000	18	5	540,000
57.119: Denominator for Outpatient Dialysis	Staff RN	500	12	5/60	500
57.120: Surgical Site Infection (SSI)	Registered Nurse (Infection Preventionist).	6,000	27	32/60	86,400
57.121: Denominator for Procedure	Staff RN	6,000	540	10/60	540,000
57.124: Paper form obsolete. See Electronic Data Upload Specification Tables.	Pharmacy Technician	6,000	12	5/60	6,000
57.125: Central Line Insertion Practices Adherence Monitoring.	Registered Nurse (Infection Preventionist).	6,000	100	5/60	50,000
57.126: MDRO or CDI Infection Form	Registered Nurse (Infection Preventionist).	6,000	72	32/60	230,400
57.127: MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring.	Registered Nurse (Infection Preventionist).	6,000	24	10/60	24,000
57.128: Laboratory-identified MDRO or CDI Event.	Registered Nurse (Infection Preventionist).	6,000	240	25/60	600,000
57.130: Denominators for Summary Vaccination Method.	Registered Nurse (Infection Preventionist).	6,000	5	14	420,000
57.133: Patient Vaccination	Registered Nurse (Infection Preventionist).	2,000	250	10/60	83,333

ESTIMATE OF ANNUALIZED BURDEN HOURS—Continued

Form number and name	Respondents	Number of respondents	Responses per respondent	Burden per response (in hours)	Total annual burden (in hours)
57.137: Patient Safety Component—Annual Facility Survey for LTCF.	Registered Nurse (Infection Preventionist).	250	1	25/60	104
57.138: Laboratory-identified MDRO or CDI Event for LTCF.	Registered Nurse (Infection Preventionist).	250	8	30/60	1,000
57.139: MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF.	Registered Nurse (Infection Preventionist).	250	3	7/60	88
57.140: Urinary Tract Infection (UTI) for LTCF	Registered Nurse (Infection Preventionist).	250	9	30/60	1,125
57.202: Healthcare Worker Survey	Occupational Health RN/Specialist.	600	100	10/60	10,000
57.203: Healthcare Personnel Safety Monthly Reporting Plan.	Occupational Health RN/Specialist.	600	9	10/60	900
57.204: Healthcare Worker Demographic Data ...	Occupational Health RN/Specialist.	600	200	20/60	40,000
57.205: Exposure to Blood/Body Fluids	Occupational Health RN/Specialist.	600	50	1	30,000
57.206: Healthcare Worker Prophylaxis/Treatment.	Occupational Health RN/Specialist.	600	10	15/60	1,500
57.207: Follow-Up Laboratory Testing	Laboratory Technician ..	600	100	15/60	15,000
57.208: Healthcare Worker Vaccination History ..	Occupational Health RN/Specialist.	600	300	10/60	30,000
57.210: Healthcare Worker Prophylaxis/Treatment—Influenza.	Occupational Health RN/Specialist.	600	50	10/60	5,000
57.211: Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel.	Occupational Health RN/Specialist.	600	1	10/60	100
57.212: Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel.	Occupational Health RN/Specialist.	600	1	10/60	100
57.213: Healthcare Personnel Influenza Vaccination Monthly Summary.	Occupational Health RN/Specialist.	6,000	6	2	72,000
57.300: Hemovigilance Module Annual Survey ...	Medical/Clinical Laboratory Technologist.	500	1	2	1,000
57.301: Hemovigilance Module Monthly Reporting Plan.	Medical/Clinical Laboratory Technologist.	500	12	2/60	200
57.303: Hemovigilance Module Monthly Reporting Denominators.	Medical/Clinical Laboratory Technologist.	500	12	30/60	3,000
57.304: Hemovigilance Adverse Reaction	Medical/Clinical Laboratory Technologist.	500	120	10/60	10,000
57.305: Hemovigilance Incident	Medical/Clinical Laboratory Technologist.	500	72	10/60	6,000
Total Est Annual Burden Hours	.....	.....	.....	.....	3,914,125

Dated: October 5, 2010.

Carol E. Walker,

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

[FR Doc. 2010–25695 Filed 10–12–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–11–0729]

Proposed Data Collections Submitted for Public Comment and Recommendations

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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 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

Customer Surveys Generic Clearance for the National Center for Health Statistics (0920–0729 exp. 6/30/2009)—Reinstatement—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on "the extent and nature of illness and disability of the population of the United States." This is a reinstatement request for a generic