

Itemized IC Revisions and Justifications

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.100	NHSN Registration Form	No change	Changed the CMS identifiers used to register.	To clarify which CMS number facilities should use to enroll in NHSN. No change in burden.
57.101	Facility Contact Information	No change	<ol style="list-style-type: none"> 1) Added question: Was this facility operational in the survey year? 2) Added Biovigilance to list of NHSN Component options. 3) Changed CMS identifier descriptions. 	<ol style="list-style-type: none"> 1) To allow facilities to specify whether they were in operation the year for which they are completing their first survey. 2) To allow facility to enroll in the BV Component that went live in 2010. 3) To clarify which CMS number facilities should use to enroll in NHSN. <p>These changes do not result in a significant change to the previously estimated response burden of 10 minutes for this form.</p>
57.102	N/A-Remove from ICR	Agreement to Participate and Consent	Form 57.102 is being removed from the OMB ICR, with approval from ICRO. Hereafter, it will only be referred to as the "NHSN Agreement to Participate and Consent" signature page.	This is the NHSN Agreement to Participate and Consent signature page. The contact information on this form is populated in the NHSN web interface with the data collected on form 57.101. The facility only prints, signs, and mails this pre-populated form to CDC. It was included in previous OMB ICRs by mistake. Removing this form from the package results in a decrease of 1500 total burden hours.
57.103	Patient Safety Component-- Annual Facility Survey	No change	<ol style="list-style-type: none"> 1) Added 6 questions related to laboratory practices of the facility. 2) Restructured a few related questions. 	<ol style="list-style-type: none"> 1) To gather specific data on the microbiology testing practices of the laboratories that conduct the testing on the specimens collected from the patients who are reported into NHSN. NHSN HAI data will only be valid and accurate if we document that the testing practices of the reporting laboratories are in accordance with the current CLSI standards and recommendations. 2) For clarity and ease of response for the user. <p>These changes result in a net increase of 10 minutes per response for this form, equating to an increase of 1,000 annual burden hours.</p>
57.104	Patient Safety Component-- Outpatient Dialysis Center	Dialysis Survey	<ol style="list-style-type: none"> 1) Added 7 questions that reflect updated HICPAC recommendations, 	<ol style="list-style-type: none"> 1) These additional questions are essential to assessing current practices. 2) These outdated questions were

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	Practices Survey		<p>CMS requirements, and recently developed best practices for BSI prevention.</p> <p>2) Deleted 3 outdated questions</p> <p>3) Streamlined or reduced complexity of 6 questions.</p> <p>4) Increased total response population from 225 to 5500.</p>	<p>no longer useful.</p> <p>3) To reduce response burden.</p> <p>4) Expansion of the survey from a limited sample to all outpatient dialysis facilities in the US will aid in meeting the prevention objectives identified in the HHS healthcare-associated infection (HAI) tier 2 action plan and provide measures for Healthy People (HP) 2020 goals. The ability to assess national practices, rates of vaccination and infection prevalence in dialysis centers has been deemed a priority by HHS. This survey is currently the only mechanism for measuring vaccination rates to permit assessment of progress toward HP 2020 objectives. CMS has also expressed interest in re-establishing the national scope of this survey to permit assessment of practices in all Medicare-certified dialysis centers for quality improvement purposes.</p> <p>Expanding the scope of the survey results in an estimated annual increase of 5,275 hours for this form.</p>
57.105	Group Contact Information	No change	No changes	NA
57.106	Patient Safety Monthly Reporting Plan	No change	<p>1) Redefined Medication-Associated Module surveillance options.</p> <p>2) Renamed MDRO and CDAD Module to MDRO and CDI Module.</p> <p>3) Redefined MDRO and CDI Module Location options.</p> <p>4) Added MDRO and CDI Module "Blood Specimen Only" option.</p> <p>5) Renamed High Risk Inpatient Influenza Vaccination Module to Vaccination Module.</p> <p>6) Redefined Vaccination Module surveillance options.</p>	<p>All: User clarifications that do not result in a change in burden for data collected on this form.</p>
57.108	Primary	No change	1) Removed CSEP as a	1) This specific event type is no

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	Bloodstream Infection (BSI)		<p>specific event as well as its specific event criteria.</p> <p>2) Updated pathogens and antimicrobials.</p>	<p>longer collected in NHSN.</p> <p>2) To match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information that is reported by clinical microbiology laboratories to physicians who treat HAIs.</p> <p>The additional pathogens and antimicrobials added to this form result in an estimated increase of 2 minutes per response, which equates an increase of 7,200 hours for this form.</p>
57.109	Dialysis Event	No change	<p>1) Local access site infections will now be collected as an event.</p> <p>2) Hospitalizations have been changed from an event to an outcome.</p> <p>3) Four items have been added to and one subtracted from the problem list.</p> <p>4) Increased total response population from 225 to 500.</p>	<p>1) To collect this valid event type.</p> <p>2) Previously, all hospitalizations were reported, including hospitalizations for noninfectious reasons. Now the user will only be required to indicate whether or not a patient was hospitalized if they meet one of the 3 infection event criteria. This change represents a <i>major</i> decrease in burden, and will eliminate more than 50% of all events reported.</p> <p>3) Changes to the problem list are data elements the renal community requested that CMS consider including in infection-related quality measures. Their inclusion will enhance usability and acceptability of the data among key stakeholders.</p> <p>4) The scope of data collection has expanded to accommodate state-mandated reporting to NHSN, CDC prevention initiatives, and CMS requirements that all dialysis facilities conduct infection surveillance.</p> <p>The changes in required event-type reporting result in a decrease in the number of responses expected per user from 200 to 75 per year, while the response population has been increased from 225 to 500. With respect to these changes, the change in total estimated annualized burden is a decrease of 1,875 burden hours for this form.</p>
57.111	Pneumonia (PNEU)	No change	Updated pathogens and antimicrobials.	To match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information

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				that is reported by clinical microbiology laboratories to physicians who treat HAIs. The additional pathogens and antimicrobials added to this form result in an estimated increase of 2 minutes per response, which equates to an increase of 14,400 hours for this form.
57.112	N/A-Remove from ICR	Any Patient - Pneumonia Flow Diagram	Obsolete. Remove from ICRAS.	This was a decision flow chart, not a form, and is no longer in use. This form number will not be included in future burden tables.
57.113	N/A-Remove from ICR	Infant and Children - Pneumonia Flow Diagram	Obsolete. Remove from ICRAS.	This was a decision flow chart, not a form, and is no longer in use. This form number will not be included in future burden tables.
57.114	Urinary Tract Infection (UTI)	No change	Updated pathogens and antimicrobials.	To match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information that is reported by clinical microbiology laboratories to physicians who treat HAIs. The additional pathogens and antimicrobials added to this form result in an estimated increase of 2 minutes per response, which equates to a net increase of 5,400 hours for this form.
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	No changes	NA
57.117	Denominators for Specialty Care Area (SCA)	No change	No changes	NA
57.118	Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	No change	No changes	NA
57.119	Denominator for Outpatient Dialysis	No change	1) Changed the terminology of vascular access types. 2) Increased total response population from 225 to 500.	1) To reflect vascular types presently in use. 2) The scope of data collection has expanded to accommodate state-mandated reporting to NHSN, CDC prevention initiatives, and CMS requirements that all dialysis facilities conduct infection surveillance. Expanding the scope of the survey results in an estimated annual

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57.120	Surgical Site Infection (SSI)	No change	Updated pathogens and antimicrobials.	<p>increase of 332 hours for this form.</p> <p>To match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information that is reported by clinical microbiology laboratories to physicians who treat HAIs. The additional pathogens and antimicrobials added to this form result in an estimated increase of 2 minutes per response, which equates to a net increase of 5,400 hours for this form.</p>
57.121	Denominator for Procedure	No change	Stratified risk factor data collection by procedure type.	<p>There are 10 general surgical risk factors currently required for each of the 40 NHSN operative procedures that can be reported to NHSN. To better predict the risk of surgical site infection, we conducted multivariable modeling of these factors as well as reported patient- and facility-level factors and have determined that we can reduce the number of general surgical risk factors to 6 for all NHSN operative procedures. Currently, for 5 of the NHSN operative procedures, between 1 and 4 additional factors are also required. Again, based on the models, we have determined that we can eliminate one of these factors for one of these procedures. Two of the 3 general surgical risk factors we propose adding for this data collection are new (diabetes mellitus, height, and weight). We estimate that there will be a small increase in the per response burden (from 8 minutes to 10 minutes) to account for these changes. However, a facility's overall burden may vary depending on which NHSN operative procedures are selected for reporting. For example, if a facility chooses to monitor any of the 11 procedures that require only the 6 general surgical risk factors, its burden may be less than a facility that monitors any of the 10 procedures that require 9 factors. The changes made to this form results in a burden increase of approximately 2 minutes per response, equating to an increased estimated burden of 108,000 hours</p>

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57.123	Antimicrobial Use and Resistance (AUR)- Microbiology Data Electronic Upload Specification Tables	Antimicrobial Use and Resistance (AUR) - Microbiology Laboratory Data	The data will be collected via monthly CDA upload only. Individual, manual entry of this data will be completely eliminated. The data collected on this form will be downloaded from the facilities' existing software, packaged into an XML file, and uploaded directly into NHSN. Data transfer will occur once per month and is expected to take, at most, 5 minutes per monthly data transfer.	per year. Previously, collection and reporting this data put considerable burden on the respondents. We have discontinued manual data collection and entry of these data for ALL facilities. In a future release of NHSN, we will make available electronic data collection and upload via Clinical Document Architecture (CDA) for these data. Facilities will only be able to enter this data via monthly data transfer. Due to the decrease in number of responses and the considerable decrease in response burden, this change eliminates 804,000 burden hours from the ICR.
57.124	Antimicrobial Use and Resistance (AUR)- Pharmacy Data Electronic Upload Specification Tables	Antimicrobial Use and Resistance (AUR) - Pharmacy Data	The data will be collected via monthly CDA upload only. Individual, manual entry of this data will be completely eliminated. The data collected on this form will be downloaded from the facilities' existing software, packaged into an XML file, and uploaded directly into NHSN. Data transfer will occur once per month and is expected to take, at most, 5 minutes per monthly data transfer.	Previously, collection and reporting this data put considerable burden on the respondents. We have discontinued manual data collection and entry of these data for ALL facilities. In a future release of NHSN, we will make available electronic data collection and upload via Clinical Document Architecture (CDA) for these data. Facilities will only be able to enter this data via monthly data transfer. Due to the decrease in number of responses and the considerable decrease in response burden, this change eliminates 426,000 burden hours from the ICR.
57.125	Central Line Insertion Practices Adherence Monitoring	No change	<ol style="list-style-type: none"> 1) Removed PICC and IV Team specifications from the "Occupation of Inserter question." 2) The "hand hygiene" and "prep agent dry" and "reason for insertion" questions have been clarified. 3) The "maximal sterile barrier" questions have been linked in the electronic data entry application to a single aggregate question, so a "Yes" response to that one question will auto-fill all five answers. 4) Added four questions: 	1-5) The Central Line Insertion Practices Adherence Monitoring form has been revised for two main reasons: 1) to make data collection and entry for the existing questions easier for the user and 2) to ensure that the data collected will provide the necessary measures to calculate the relevant HHS Action Plan National Metric and to indicate and track adherence to the updated CDC "Guidelines for Prevention of Intravascular Catheter-Related Infections". In addition, we will now ask whether or not central line placement attempt was successful. Currently recorders enter a central line insertion

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			<p>the user will now indicate whether the central line was placed emergently, if ultrasound guidance was used, if attempt resulted in successful central line placement, and if there was a patient contraindication to chlorhexidine.</p> <p>5) Two questions were removed from the form, because they are not considered important for measure of appropriate central line insertion adherence. One additional question was changed from required to conditionally required only if the insertion was due to central line replacement, and asks if the insertion was exchanged over a guide wire.</p>	<p>practice (CLIP) event for every attempted central line placement, whether it was successful or not. Because the risk of central line-associate bloodstream infection (CLABSI) from an unsuccessful line insertion is thought to be negligible, adding this question informs data analysis attempts to associate line insertions with CLABSI occurrence. Obtaining the information about the number of unsuccessful attempts may assist in determining whether unsuccessful attempts are in fact related to subsequent CLABSI.</p> <p>Overall, these changes result in a simplification of data entry; therefore the response burden has been revised from 10 minutes to 5 minutes for this form, resulting in a reduction of 50,000 burden hours from the ICR.</p>
57.126	MDRO or CDI Infection Form	MDRO Infection Form	<p>1) Changed title of form to "MDRO or CDI Infection Event." 2) Updated pathogens and antimicrobials.</p>	<p>1) All references to CDAD anywhere in the module and the guidance materials are being updated to CDI. This revision is occurring to keep the module and NHSN current and consistent with the correct reference terminology that is being used by the scientific community of <i>C. difficile</i> experts. The use of CDAD is outdated and no longer holds the correct meaning when referring to disease caused by the <i>C. difficile</i> pathogen.</p> <p>2) To match the current Clinical Laboratory Standards Institute (CLSI) testing panels and the information that is reported by clinical microbiology laboratories to physicians who treat HAIs.</p> <p>The additional pathogens and antimicrobials added to this form result in an estimated increase of 2 minutes per response, which equates to a net increase of 14,400</p>

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57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	Multi-drug Resistance Organism (MDRO) Prevention Process and Outcome Measures Monthly Monitoring Form	<ol style="list-style-type: none"> 1) Changed name of form to "MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring" 2) Added additional spaces for denominator days to be entered for facility-wide locations. 3) Added a line for LabID Event (Blood specimens only) 	<p>hours for this form.</p> <ol style="list-style-type: none"> 1) All references to CDAD anywhere in the module and the guidance materials are being updated to CDI. This revision is occurring to keep the module and NHSN current and consistent with the correct reference terminology that is being used by the scientific community of <i>C. difficile</i> experts. The use of CDAD is outdated and no longer holds the correct meaning when referring to disease caused by the <i>C. difficile</i> pathogen. 2) The MDRO and CDAD Module protocol has always stated that if a facility is monitoring <i>C. difficile</i> LabID Events at the facility-wide location level then counts from any neonatal intensive care and well baby locations must be subtracted from facility-wide denominator totals to be used for the calculated <i>C. difficile</i> rates. Until now, we had neglected to provide variable spaces for the user to be able to enter these three required separate <i>C. difficile</i> denominator counts. Three new variables, Patient Days, Patient Admissions, and Encounters for <i>C. difficile</i>, have been added for this specific instance when separate <i>C. difficile</i> denominator counts will be required according to a facility's choice for reporting. 3) To allow facilities the option of reporting blood specimen events to simplify their reporting burden. <p>These changes do not result in a change in burden for this form.</p>
57.128	Laboratory-identified MDRO or CDI Event	Laboratory-identified MDRO Event	<ol style="list-style-type: none"> 1) Changed name of form to "MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring". 2) Split "Specimen Source" question into two categories. 3) Removed "Documented prior..." 	<ol style="list-style-type: none"> 1) All references to CDAD anywhere in the module and the guidance materials are being updated to CDI. This revision is occurring to keep the module and NHSN current and consistent with the correct reference terminology that is being used by the scientific community of <i>C. difficile</i> experts. The use of CDAD is outdated and no longer holds

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			<p>question.</p> <p>4) Require "Patient Discharged..." question for both MDRO and CDI Events.</p>	<p>the correct meaning when referring to disease caused by the <i>C. difficile</i> pathogen.</p> <p>2) To enable users to quickly identify and choose the source from shorter and more focused lists.</p> <p>3) System is able to autofill this question using previously-entered event data.</p> <p>4) To better inform the facilities of the incoming prevalent burden of these important organisms that may be attributed to a previous inpatient stay at the same facility.</p> <p>The Laboratory-Identified (LabID) Event form has been revised for ease of data entry and to increase standardization across all users for appropriate comparative reasons and for viable data collection through electronic data capture. The simplifications allow us to decrease the estimated burden of each response, equating to a reduction of 120,000 burden hours for this form.</p>
<p>57.130</p>	<p>Vaccination Monthly Monitoring Form-Summary Method</p>	<p>High Risk Inpatient Influenza Vaccination Monthly Monitoring Form - Method A</p>	<p>1) Changed name of form.</p> <p>2) Changed count of inpatients meeting high-risk criteria to all inpatients six months or older.</p> <p>3) Removed monthly count of "high-risk inpatients not previously vaccinated" from form.</p>	<p>1) The current influenza vaccination recommendation includes all persons six months old or older, which makes the concept of "high risk" no longer valid for influenza vaccination surveillance. "The High Risk Inpatient Influenza Vaccination Module" and associated forms (57.130-57.134) will henceforth be referred to as the "Vaccination Module."</p> <p>2) To capture all inpatients recommended for influenza vaccination for the month of surveillance.</p> <p>3) The count and classification of high-risk inpatients is no longer valid</p> <p>The changes made to this form results in a burden decrease of approximately 2 hours per response, equating to a decreased estimated burden of 60,000 hours per year.</p>
<p>57.131</p>	<p>Vaccination Monthly Monitoring Form-Patient-</p>	<p>High Risk Inpatient Influenza Vaccination</p>	<p>Removed this question: "Total # of patients meeting high risk criteria previously vaccinated"</p>	<p>The current influenza vaccination recommendation includes all persons six months old or older, which makes the concept of "high</p>

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	Level Method	Monthly Monitoring Form - Method B	during current influenza season.”	risk” no longer valid for influenza vaccination surveillance. The changes made to this form results in a burden decrease of approximately 2 hours per response, equating to a decreased estimated burden of 20,000 hours per year.
57.132	N/A-Remove from ICR	High Risk Inpatient Influenza Vaccination Method B Form-Part 1	The data collected on this form is being combined with form 57.133, rendering this form obsolete. Form 57.132 should be removed from ICRAS.	The data collected on this form pertained primarily to high-risk inpatients and their underlying conditions. Because influenza vaccination recommendation is no longer limited to high-risk inpatient populations, it is no longer necessary to capture this information. The only information left on this form is the “date admitted to the facility”, which has been moved to form 57.133. The removal of this form results in a burden decrease of 41,667 hours in the ICR.
57.133	Patient Vaccination	High Risk Inpatient Influenza Vaccination Method B Form-Part 2	Moved one question from form 57.132: “Date admitted to facility.”	Consolidated forms 57.132 and 57.133. The single question added to form 57.133 does not increase the estimated response burden.
57.135	N/A-Remove from ICR	List of Blood Isolates	Obsolete. Remove from ICRAS.	This form was developed for potential use as a validation for electronic data capture but was never put into use. We do not foresee ever implementing this form and would like to remove it from this ICR. Removal of this form from the package saves 6,000 total burden hours.
57.136	N/A-Remove from ICR	Manual Categorization of Positive Blood Cultures	Obsolete. Remove from ICRAS.	This form was developed for potential use as a validation for electronic data capture but was never put into use. We do not foresee ever implementing this form and would like to remove it from this ICR. Removal of this form from the package saves 6,000 total burden hours.
57.137	Patient Safety Component-- Annual Facility Survey for LTCF	N/A-This is a new form.	These four forms, intended for use in long-term care facilities (LTCFs), are adaptations of previously-approved NHSN data collection forms specific to acute-	LTCFs are highly regulated at the federal level by the Centers for Medicare and Medicaid Services (CMS). CMS released a revised version of the “Interpretive Guidance for Infection Control in Nursing Homes - F441” in
57.138	Laboratory-identified	N/A-This is a new form.		

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57.139	MDRO or CDI Event for LTCF MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	N/A-This is a new form.		
57.140	Urinary Tract Infection (UTI) for LTCF	N/A-This is a new form.	care facilities. NHSN plans to expand its current HAI surveillance population to include LTCFs in the near future to support CMS and HHS HAI directives toward HAI surveillance in this setting. As the LTCF HAI data collection capabilities will be built within the existing NHSN web interface, we request approval of these forms as a revision the current NHSN ICR (0920-0666).	September 2009 which sets an expectation for LTCFs to perform HAI surveillance as part of their infection control program activity. However, no current standardized methodology for defining and reporting HAIs exists in this setting. The use of the NHSN system in acute care hospitals for setting national benchmarks and supporting facility-level quality improvement activity serves as a model for addressing the same HAI reporting needs in LTCFs. Adapting the current HAI reporting forms for LTCFs required only small changes and will
57.200	Healthcare Personnel Safety Component Annual Facility Survey	No change	No changes	The data collected on this form has not changed, however the total number of respondents is being revised from 600 to 6000 to include all acute care facilities expected to enroll in NHSN to submit the Healthcare Personnel Influenza Vaccination Monthly Summary (57.213) in accordance with proposed CMS requirements. The net burden increase for this revision is 43,200 hours. See expanded justification for form 57.213.
57.202	Healthcare Worker Survey	No change	No changes	NA
57.203	Healthcare Personnel Safety Monthly Reporting Plan	Healthcare Personnel Safety Reporting Plan	No changes	NA
57.204	Healthcare Worker Demographic Data	No change	No changes	NA

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57.205	Exposure to Blood/Body Fluids	No change	No changes	NA
57.206	Healthcare Worker Prophylaxis/Treatment	No change	No changes	NA
57.207	Follow-Up Laboratory Testing	Laboratory Testing	No changes	NA
57.208	Healthcare Worker Vaccination History	No change	No changes	NA
57.209	Healthcare Worker Influenza Vaccination	No change	Added product types for non-seasonal influenza vaccination types.	To capture vaccination events related to non-seasonal influenza vaccinations. These changes do not change the burden estimates for this form.
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	Healthcare Worker Influenza Antiviral Medication Administration	Changed name of form to "Healthcare Worker Prophylaxis/Treatment-Influenza."	To more accurately describe the data collected on this form. These changes do not change the burden estimates for this form.
57.211	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel	No change	1) Added "Vaccination Campaign" question at beginning of form. 2) Added #11.	1) To characterize the type of vaccination effort undertaken at facility. 2) To document vaccine safety information date. These changes do not change the burden estimates for this form.
57.212	Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel	No change	Added "Vaccination Campaign" question at beginning of form.	To characterize the type of vaccination effort undertaken at facility. These changes do not change the burden estimates for this form.
57.213	Healthcare Personnel Influenza Vaccination Monthly Summary	N/A-This is a new form.	1) Currently, the data collection tool for this module focuses on individual-level vaccination and declination data. This data collection form is a summary version of the individual vaccination forms contained in this module. 2) Increased total number of facilities that would also complete the HPS	1) This new form would collect aggregated monthly data on seasonal and non-seasonal influenza vaccination coverage among healthcare personnel. The tool would include numbers of healthcare personnel vaccinated by month, those who declined vaccine, and those who received vaccine elsewhere. These data would provide summary statistics on the uptake of influenza vaccine in healthcare facilities, and with the current facility surveys already required each year by the NHSN,

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			Annual Facility Survey to the maximum number of Acute Care Facilities in the US (6000) eligible to participate in the HPS Component of NHSN.	<p>measures of vaccine coverage may be stratified by healthcare facility size or type. Piloting work for this tool is ongoing among key stakeholders, including collaborations with the National Center for Immunization and Respiratory Diseases, and with the Centers for Medicare and Medicaid Services (CMS). It is anticipated that CMS will include this aggregated measure of influenza vaccination coverage as a future reporting requirement for hospitals' annual reimbursement.</p> <p>2) It is projected that enrollment in this module will likely increase the number of participating facilities if reporting can be submitted in summary form. Annual facility survey reports would also increase proportionally to reflect the rise in healthcare facility enrollments.</p> <p>This new form adds an estimated 72,000 burden hours to this ICR.</p>
57.300	Hemovigilance Module Annual Survey	No change	<p>1) Added question: Does your healthcare facility provide all of its own transfusion services, including all laboratory functions?</p> <p>2) Formatting changes.</p>	<p>1) Gain a better understanding of the physical and functional structure of healthcare facilities and their transfusion medicine departments.</p> <p>2) Improved usability. The additional question does not change the previously estimated burden of 2 hours for this annual survey.</p>
57.301	Hemovigilance Module Monthly Reporting Plan	No change	Formatting changes only.	Improved usability. No change in burden.
57.302	Hemovigilance Module Monthly Incident Summary	Hemovigilance Module Monthly Incident Summary	<p>1) Changed the name of form.</p> <p>2) Formatting changes.</p>	<p>1) Minimize User confusion.</p> <p>2) Improved usability. No change in burden.</p>
57.303	Hemovigilance Module Monthly Reporting Denominators	No change	Formatting changes only.	Improved usability. No change in burden.
57.304	Hemovigilance Adverse Reaction	No change	<p>1) Added an additional Gender option of 'Other.'</p> <p>2) Changed a single</p>	<p>1) To be consistent with other two NHSN Components.</p> <p>2) Better able to analyze data with defined options.</p>

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			question's text response to one with defined options. 3) Formatting changes.	3) Improved usability. The addition of defined options does not change the previously estimated burden of 10 minutes for this event form.
57.305	Hemovigilance Incident	No change	Formatting changes only.	Improved usability. No change in burden.