

Itemized IC Revisions and Justifications

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.100	NHSN Registration Form	No change	No changes	N/A
57.101	Facility Contact Information	No change	1) Update form to remove section for the Antimicrobial Use and Resistance Component.	1) The form was updated to remove applicable sections for the Antimicrobial Use and Resistance Component as that functionality will not be implemented within NHSN. This change does not affect the estimated burden of this form.
57.103	Patient Safety Component-Annual Hospital Survey	No change	<ol style="list-style-type: none"> 1) Removal of the section specific to Ambulatory Surgery Centers (ASCs). 2) Wording revisions on questions #2 and #20. 3) Clarified the question wording and added an additional response option for questions #14-17. 4) Clarified the question wording and answer choices for question #18. 5) Added new questions #19 and #21. 6) Re-categorized the answer choices for question #22. 7) Removed two questions within the Infection Control Practices section. 8) Added an additional response option for question #24. 9) Lowering the number of annual respondents from 6,000 to 5,000. 	<ol style="list-style-type: none"> 1) Due to the number of questions and user confusion from those in Ambulatory Surgery Centers (ASCs), ASCs will no longer complete the hospital survey. Instead, they will be directed to complete an ASC-specific survey. 2) Additional wording added to questions #2 and #20 due to user confusion. 3) Additional wording and a new answer choice added to questions #14-17 since some hospitals rarely or never admit patients with Multi-drug resistant organisms. 4) Additional wording and answer choice for question #18 to make consistent with Laboratory Practices section question #19. 5) New questions were added in order to capture infection control policies specifically around MRSA. 6) Re-categorized the answer choices for question #22 due to user confusion with previous order. 7) Two questions were removed within the Infection Control Practices section as the responses had become almost 100% unanimous and therefore were no longer needed. 8) Additional answer choice to #24 that states “co-led by both pharmacist and physician” since this was a common answer that users entered when selecting “Other” as a response from last year’s survey. 9) Removal of the ASC questions will remove roughly 1,000 respondents from the total number of respondents completing this form annually. <p>These changes result in a decrease of 833 burden hours for this form.</p>

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57.105	Group Contact Information	No change	No changes	N/A
57.106	Patient Safety Monthly Reporting Plan	No change	No changes	N/A
57.108	Primary Bloodstream Infection (BSI)	No change	No changes	N/A
57.111	Pneumonia (PNEU)	No change	1) Three response options were revised.	1) Revisions were made to response options to reflect updates to the Ventilator Associated Pneumonia surveillance protocol: Lung parenchyma was edited to read lung tissue to more clearly define the specimen source and to be in concert with the language that appears in the PNEU event protocol; Bordetella was added as an eligible pathogen in the PNEU event protocol and consequently added to the PNEU event reporting form; Tachycardia was replaced with the correct term: tachypnea. These changes do not affect the estimated burden of this form.
57.112	Ventilator-Associated Event	No change	No changes	N/A
57.114	Urinary Tract Infection (UTI)	No change	1) Revision of response options for urinary catheter status. 2) Response options were removed and/or revised for the specific event criteria section.	1) The risk factors for urinary catheter status have been reworded to avoid confusion on which to choose when a catheter has been in place for greater than 2 days and is removed on the date of event. In that case, the risk factor "In place" should be chosen rather than "Removed" which is only chosen if it is removed the day before the date of event. 2) The CAUTI criteria have been revised to more accurately reflect clinical interpretations through the removal of non-bacterial organisms as a cause, and to remove symptomatic urinary tract infection (SUTI) type 2 which had a lower colony count urine culture in order to avoid differences in reporting due solely to laboratory reporting practices. The form has had the excluded criteria removed. These changes result in a decrease of 40,000 burden hours for this form.

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57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	<ol style="list-style-type: none"> 1) Ventilator days are no longer conditionally required. 2) Guidance related to central lines and umbilical catheters was removed. 	<ol style="list-style-type: none"> 1) The double asterisk indicating “conditionally required according to the events indicated in Plan” is removed from vent data columns as NICUs can no longer perform in-plan ventilator-associated event reporting in NHSN. 2) The guidance to report a patient with both central line and umbilical line as only a central line day is removed because, umbilical lines are no longer differentiated from central lines. <p>These changes do not affect the estimated burden of this form.</p>
57.117	Denominators for Specialty Care Area (SCA)/Oncology (ONC)	No change	No changes	N/A
57.118	Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)	No change	<ol style="list-style-type: none"> 1) Increased the annual number of responses per respondent to 60. 	<ol style="list-style-type: none"> 1) The number of annual responses per respondent was increased to 60 to account for the increased use of this form due to CMS required reporting for additional location types. <p>These changes result in a net increase of 180,000 burden hours for this form.</p>
57.120	Surgical Site Infection (SSI)	No change	<ol style="list-style-type: none"> 1) Updated field for ICD-10-PCS and CPT Procedure codes. 	<ol style="list-style-type: none"> 1) The Change to ICD-10-PCS codes is needed due to the retirement of ICD-9-CM codes as of October 1, 2015. The addition of the ability to use CPT codes was based on the fact that some facilities use these and will not be using ICD-10-codes. As well as the fact that CPT codes are the usual codes used for ASCs. <p>These changes do not affect the estimated burden of this form.</p>
57.121	Denominator for Procedure	No change	<ol style="list-style-type: none"> 1) Updated field for ICD-10-PCS and CPT Procedure codes. 2) Removed response option for RFUSN 3) Removed response options for HPRO/KPRO section. 	<ol style="list-style-type: none"> 1) The Change to ICD-10-PCS codes is needed due to the retirement of ICD-9-CM codes as of October 1, 2015. The addition of the ability to use CPT codes was based on the fact that some facilities use these and will not be using ICD-10-codes. As well as the fact that CPT codes are the usual codes used for ASCs. 2) RFUSN was removed since it will no longer be its own NHSN operative procedure group. 3) There are four choices that were removed from the HPRO and KPRO details since no ICD-9-CM codes currently map to these and the decision was made to remove these from the form. <p>These changes do not affect the estimated burden of this form.</p>

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57.123	Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	No change	No changes	N/A
57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	No change	1) Seven new antimicrobials were added to the form.	1) Seven newly FDA-approved antimicrobials were added to the form to allow facilities using these drugs to submit usage data as appropriate. These changes do not affect the estimated burden of this form.
57.125	Central Line Insertion Practices Adherence Monitoring	No change	1) New fields were added for contraindication of chlorhexidine gluconate.	1) The new fields reflect updates to chlorhexidine gluconate product labeling which states "...use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns." This change results in an increase in 33,333 burden hours for this form.
57.126	MDRO or CDI Infection Form	No change	1) Revision of criteria for five elements in signs and symptoms and laboratory or diagnostic testing section.	1) "Acute onset of diarrhea" was changed to "Diarrhea" (per specific site criteria) to adhere to site specific criteria and reporting rules. "Purulent drainage or material" was changed to "Drainage or material" (per specific site criteria); and three laboratory tests options were consolidated to one "Other positive laboratory tests" (per specific site criteria) to adhere to site specific criteria and reporting rules. These changes do not affect the estimated burden of this form.
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	No change	1) Two questions revised with clarifying language.	1) Minor wording changes made to the form to improve clarification and adhere to reporting rules. These changes do not affect the estimated burden of this form.

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57.128	Laboratory-identified MDRO or CDI Event	No change	<ol style="list-style-type: none"> 1) 'Unknown' was added as an applicable response option to one question. 2) Two questions have been changed from optional to be required for completion. 3) One question was revised from '3 months' to '4 weeks.' 4) Two new questions were added to request information on carbapenemase testing. 	<ol style="list-style-type: none"> 1) 'Unknown' was added as an applicable response option to one question to adhere to reporting rules which allow event completion when previous facility discharge information is not available. 2) Two questions were changed to be required for completion to adhere to reporting rules, which support the continuity of surveillance across facilities. 3) One question was revised from '3 months' to '4 weeks' to be consistent with the current CDI categorizations. 4) Two new questions were added to request information on carbapenemase testing to adhere to new CRE reporting rules by collecting additional information in relation to CRE laboratory tests methods. <p>These changes result in an increase in 120,000 burden hours for this form.</p>
57.137	Long-Term Care Facility Component – Annual Facility Survey	No change	<ol style="list-style-type: none"> 1) One question was removed from the form. 2) Two questions were reworded. 	<ol style="list-style-type: none"> 1) The National Provider ID was removed from the form as that data is no longer used by NHSN. 2) Two questions were reworded to align with updated terminology used in infection prevention. <p>These changes do not affect the estimated burden of this form.</p>
57.138	Laboratory-identified MDRO or CDI Event for LTCF	No change	<ol style="list-style-type: none"> 1) One question was revised from '3 months' to '4 weeks.' 	<ol style="list-style-type: none"> 1) One question was revised from '3 months' to '4 weeks' to be consistent with the current CDI categorizations. <p>This change does not affect the estimated burden of this form.</p>
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	No change	No changes	N/A
57.140	Urinary Tract Infection (UTI) for LTCF	No change	No changes	N/A
57.141	Monthly Reporting Plan for LTCF	No change	No changes	N/A
57.142	Denominators for LTCF Locations	No change	No changes	N/A
57.143	Prevention Process Measures Monthly Monitoring for LTCF	No change	No changes	N/A
57.150	Patient Safety Component- Annual Facility Survey for LTAC	No change	<ol style="list-style-type: none"> 1) Clarified the wording regarding facility admissions and removed two response categories. 2) Wording revisions on questions #2 and #20. 3) Clarified the question wording and added an 	<ol style="list-style-type: none"> 1) The original question was deemed too confusing and after discussions with LTAC facility stakeholders, it was decided to re-word the question and remove two response categories as those categories were too subjective to measure appropriately. 2) Additional wording added to questions

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			<p>additional response option for questions #14-17.</p> <p>4) Clarified the question wording and answer choices for question #18.</p> <p>5) Added new questions #19 and #21.</p> <p>6) Re-categorized the answer choices for question #22.</p> <p>7) Removed three questions within the Infection Control Practices section.</p> <p>8) Added an additional response option for question #24.</p>	<p>#2 and #20 due to user confusion.</p> <p>3) Additional wording and a new answer choice added to questions #14-17 since some hospitals rarely or never admit patients with Multi-drug resistant organisms.</p> <p>4) Additional wording and answer choice for question #18 to make consistent with Laboratory Practices section question #19.</p> <p>5) New questions were added in order to capture infection control policies specifically around MRSA.</p> <p>6) Re-categorized the answer choices for question #22 due to user confusion with previous order.</p> <p>7) Three questions were removed within the Infection Control Practices section as the responses had become almost 100% unanimous and therefore were no longer needed.</p> <p>8) Additional answer choice to #24 that states “co-led by both pharmacist and physician” since this was a common answer that users entered when selecting “Other” as a response from last year’s survey.</p> <p>These changes do not affect the estimated burden of this form.</p>

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57.151	Patient Safety Component-Annual Facility Survey for IRF	No change	<ol style="list-style-type: none"> 1) Clarified the wording in the form instructions. 2) Wording revisions on questions #2 and #20. 3) Clarified the question wording and added an additional response option for questions #14-17. 4) Clarified the question wording and answer choices for question #18. 5) Added new questions #19 and #21. 6) Re-categorized the answer choices for question #22. 7) Removed three questions within the Infection Control Practices section. 8) Added an additional response option for question #24. 	<ol style="list-style-type: none"> 1) Added additional language around the instructions for bed size/patient days, etc. to clarify that these counts should be representative of the IRF only. 2) Additional wording added to questions #2 and #20 due to user confusion. 3) Additional wording and a new answer choice added to questions #14-17 since some hospitals rarely or never admit patients with Multi-drug resistant organisms. 4) Additional wording and answer choice for question #18 to make consistent with Laboratory Practices section question #19. 5) New questions were added in order to capture infection control policies specifically around MRSA. 6) Re-categorized the answer choices for question #22 due to user confusion with previous order. 7) Three questions were removed within the Infection Control Practices section as the responses had become almost 100% unanimous and therefore were no longer needed. 8) Additional answer choice to #24 that states “co-led by both pharmacist and physician” since this was a common answer that users entered when selecting “Other” as a response from last year’s survey. <p>These changes do not affect the estimated burden of this form.</p>
57.154	Antimicrobial Use & Resistance Component - Monthly Reporting Plan	No change	<ol style="list-style-type: none"> 1) This form will be removed from the package as NHSN AUR Component was not implemented. 	<ol style="list-style-type: none"> 1) After evaluation of the proposed NHSN AUR Component, it was determined that this form was no longer required as the NHSN AUR Component was not implemented in NHSN. <p>Removing this form decreases the package burden by 100 burden hours.</p>
57.200	Healthcare Personnel Safety Component Annual Facility Survey	No change	No changes	N/A

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57.203	Healthcare Personnel Safety Monthly Reporting Plan	No change	<ol style="list-style-type: none"> 1) A new response option was added to this form: 'influenza vaccination summary for the inpatient psychiatric facility unit(s).' 2) Number of respondents increased from 11,000 to 17,000. 	<ol style="list-style-type: none"> 1) This response option was added to allow facilities to separate the reporting of influenza vaccination summary data from the inpatient psychiatric facility units for CMS reporting purposes. 2) Due to an increase in CMS required reporting of influenza vaccination summary data, this form must be completed by all inpatient psychiatric facilities and outpatient dialysis centers in CMS reporting programs. Therefore, the number of respondents using this form has been increased to 17,000. <p>These changes result in a net increase of 500 burden hours for this form.</p>
57.204	Healthcare Worker Demographic Data	No change	No changes	N/A
57.205	Exposure to Blood/Body Fluids	No change	No changes	N/A
57.206	Healthcare Worker Prophylaxis/Treatment	No change	No changes	N/A
57.207	Follow-Up Laboratory Testing	No change	No changes	N/A
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	No change	No changes	N/A
57.300	Hemovigilance Module Annual Survey	No change	<ol style="list-style-type: none"> 1) The order of the check box answer choices for type of teaching hospital was changed. 2) 'Other Accrediting Org' was changed to 'Other Accrediting Organization.' 3) Trauma and ED' was changed to 'Trauma/Emergency' and 'Obstetrics and gynecology' was changed to 'Obstetrics/gynecology.' 4) 'Dedicated physicians', 'MLTs', and 'MTs' was changed to 'physicians', 'medical laboratory technicians', and 'medical technologists', respectively. 5) The word 'cellular' was added to 'leuko-poor components.' 6) One question was added to ask facilities to indicate their average pool size. 	<ol style="list-style-type: none"> 1) The order of the check box answer choices for type of teaching hospital was changed. This was done to align with other annual surveys in NHSN. 2) 'Other Accrediting Org' was changed to 'Other Accrediting Organization.' The abbreviation was expanded for clarification. 3) Trauma and ED' was changed to 'Trauma/Emergency' and 'Obstetrics and gynecology' was changed to 'Obstetrics/gynecology' for clarification. 4) 'Dedicated physicians', 'MLTs', and 'MTs' was changed to 'physicians', 'medical laboratory technicians', and 'medical technologists', respectively. These changes were made to expand the abbreviations for clarity and an instructional sentence was added. 5) The word 'cellular' was added to 'leuko-poor components' for clarification. 6) Facilities report two types of pooled products. Currently, data collection for these two types of pooled products are different. The addition of this question will add consistency the way pooled product data are collected. <p>These changes do not affect the estimated burden of this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.301	Hemovigilance Module Monthly Reporting Plan	No change	No changes	N/A
57.303	Hemovigilance Module Monthly Reporting Denominators	No change	<ol style="list-style-type: none"> 1) One required question will be added to the form to assess whether facilities transfuse pathogen-reduced products. 2) A conditional question table will be added to summarize the total number of pathogen-reduced units transfused by product type. 	<ol style="list-style-type: none"> 1) One required question will be added to the form to assess whether facilities transfuse pathogen-reduced products. Pathogen reduction technology is a method used to reduce the risk of transfusion transmitted infections. Psoralen + UV light is a pathogen reduction technology recently approved by the FDA. The mandatory question will allow for understanding of industry uptake of psoralen-treated product. 2) The conditional question with table will allow for calculation of transfusion reaction rates for psoralen-treated products. <p>These changes do not affect the estimated burden of this form.</p>
57.304	Hemovigilance Adverse Reaction	No change	<ol style="list-style-type: none"> 1) A check box will be added to the Adverse Reaction form to allow users to mark reports to be shared with FDA. 	<ol style="list-style-type: none"> 1) NHSN HV Module will be one mechanism for facilities to report transfusion reaction that meet the Safety Reporting Rule requirement to FDA. Facilities will check the box if the report is to be shared with FDA. This reporting mechanism will reduce reporting burden for facilities that report transfusion reactions to both NHSN HV Module and FDA. <p>This change does not affect the estimated burden of this form.</p>
57.305	Hemovigilance Incident	No change	<ol style="list-style-type: none"> 1) The question ‘If Yes, result(s) of analysis: (check all that apply)’ and all options will be removed from the Investigation Results section. 	<ol style="list-style-type: none"> 1) The conditional question conflicts with Patient Safety Organization rules. The Agency for Healthcare Research and Quality (AHRQ) requested the question be removed. The question is not used for NHSN BV analysis. <p>This change does not affect the estimated burden of this form.</p>
57.400	Patient Safety Component—Annual Facility Survey for Ambulatory Surgery Center (ASC)	Outpatient Procedure Component—Annual Facility Survey	<ol style="list-style-type: none"> 1) The name of the form was changed. 2) One question was removed. 3) Two questions were reworded. 	<ol style="list-style-type: none"> 1) The name of the form was changed to align with the movement of this form from the Outpatient Procedure Component to the Patient Safety Component. 2) One question was removed since all respondents would have been answering the question in the same way therefore providing no additional information to NHSN. 3) Two questions were reworded for clarification. <p>These changes do not affect the estimated burden of this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.401	Outpatient Procedure Component - Monthly Reporting Plan	No change	No changes	N/A
57.402	Outpatient Procedure Component Event	No change	No changes	N/A
57.403	Outpatient Procedure Component - Monthly Denominators and Summary	No change	No changes	N/A
57.500	Outpatient Dialysis Center Practices Survey	No change	<ol style="list-style-type: none"> 1) Added question for patient population served by respondent facility. 2) Removed question assessing how many patients received at least 3 doses of hepatitis B vaccine. 3) Added question to assess number of patients receiving pneumococcal vaccine. 4) Added question to assess number of patients who reverse seroconverted. 5) Added question to assess how many patients reuse dialyzers. 6) Added question to assess facility's water quality. 7) Added question to assess type of reused dialyzer. 8) Added question to assess how dialyzer is reprocessed. 9) Added question to assess how antibiotics are administered to patients within the facility. 10) Added question to assess skin preparation prior to buttonhole cannulation. 11) Revisions of question and response wording. 	<ol style="list-style-type: none"> 1) Added "What patient population does your center serve?" to capture whether facility patients are adult, pediatric, or mixed adult and pediatric, each of which may have different risk factors and practices. 2) "Of your center's maintenance, non-transient home hemodialysis patients from question 17.b., how many received at least 3 doses of hepatitis B vaccine (ever)?" was removed because it did not fit in with the new categories established in question 20. 3) Added "Of the in-center hemodialysis patients counted in question 17a, how many received at least one dose of pneumococcal vaccine (ever)?" to determine the number of in-center hemodialysis patients (subset of patients in Q19) who have received the pneumococcal vaccine. Also parallels the structure of question 19. 4) Added the question "In the past year, has your center ≥1 hemodialysis patients who reverse seroconverted (i.e., had evidence of resolved hepatitis B infection followed by reappearance of hepatitis B surface antigen)?" to estimate the national prevalence with which reverse hepatitis B virus seroconversion occurs. 5) Added "Of the maintenance, non-transient in-center hemodialysis patients counted in 17a, how many of them participate in dialyzer reuse?" to determine the national prevalence of dialyzer reuse, a potential risk factor for bloodstream infections and outbreaks. 6) Added "Does your center routinely test reverse osmosis (R.O.) water from the reuse room for culture and endotoxin whenever a reuse patient has a pyrogenic reaction?" to assess the national extent of this practice, which can help inform if the facility's water is compromised and placing patients at risk. 7) Added "Of all reused dialyzers in your

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				<p>center, how many of them have sealed (non-removable) header caps?” to determine how common these device types are, which when reused, may be a risk factor for inadequate cleaning and subsequently cause bloodstream infections.</p> <p>8) Added “How are dialyzers reprocessed? Automated/Manually” to determine the prevalence of each practice, which may be a risk factor for bloodstream infections among reuse patients.</p> <p>9) Added “In your center, how often are antibiotics administered for a suspected bloodstream infection before blood cultures are drawn (or without performing blood cultures)?” to assess the extent of this recommended practice, both for patient care and antimicrobial stewardship.</p> <p>10) Added “Before cannulation, what is the buttonhole site most often prepped with?” to determine if prep practices vary for buttonhole cannulation patients.</p> <p>11) After internal and external review, many of the questions and response options have been edited for clarification purposes.</p> <p>These changes result in a net increase of 1,625 burden hours for this form.</p>
57.501	Dialysis Monthly Reporting Plan	No change	No changes	N/A
57.502	Dialysis Event	No change	<p>1) Added a new question to assess whether the patient’s dialyzer was reused.</p> <p>2) Added a new question to assess whether the antibiotic start was new or a continuation.</p>	<p>1) Added “Patient’s dialyzer is reused? Yes/No” because dialyzer reuse has been identified as important risk factor for infection. By including this field on both numerator and denominator forms, it will be possible to calculate a dialyzer reuse rate.</p> <p>2) Added “Was this a new outpatient start or a continuation of an inpatient course?” to determine the proportion of antimicrobial starts dialysis facilities report that occur as a result of inpatient care and are outside of the dialysis facility’s control.</p> <p>These changes result in a net increase of 32,500 burden hours for this form.</p>

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57.503	Denominators for Dialysis Event Surveillance	No change	1) Added a question to assess the number of patients for whom dialyzers are reused.	1) Added “Number of these patients for whom dialyzers are reused” because dialyzer reuse has been identified as important risk factor for infections. By including this field on both numerator and denominator forms, it will be possible to calculate a dialyzer reuse rate. These changes result in a net increase of 5,200 burden hours for this form.
57.504	Prevention Process Measures Monthly Monitoring for Dialysis	No change	1) Modified existed question.	1) Feedback from users indicates that auditing injection safety is best done in two parts: assessment of medication preparation process (which is typically completed for multiple patients at one time at a specific med prep area) and medication administration (which is completed one patient at a time at the patient’s chair). So the current summary data collection field has been separate into two to track audit results for each part of injection safety separately. These changes result in a net increase of 13,500 total burden hours for this form.
57.505	Dialysis Patient Influenza Vaccination	No change	No changes	N/A
57.506	Dialysis Patient Influenza Vaccination Denominator	No change	No changes	N/A
57.600	State Health Department Validation Record	No change	1) This form will be removed from the package as this form was not implemented in NHSN.	1) After evaluation of the proposed State Health Department Validation Record, it was determined that this form was no longer required as the functionality was not implemented in NHSN. Removing this form decreases the package burden by 1,900 burden hours.