Itemized IC Revisions and Justifications

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.100	NHSN Registration Form	No change	No change	N/A
57.101	Facility Contact Information	No change	No change	N/A
57.103	Patient Safety Component-Annual Hospital Survey	No change	 Addition of questions #12 & #13 to indicate pathogen identification methods. Added optional Facility Water Management and Monitoring Program section #36, #37, and #38. 	 The purpose of these questions are to understand and identify the primary and definitive methods used by facilities to identify microbes from blood cultures collected. Questions that identify the microbe collection methods will inform decisions on risk adjustment. Multiple users have made requests to take advanced methodology (MALDI-TOF) into consideration because facilities are being penalized for missing more precise organism identification. For question #36, a facility risk assessment is an import first step to identify areas where <i>Legionella</i> and other waterborne pathogens could grow and spread. The assessment may inform the water management program by identifying areas or devices in the building where <i>Legionella</i> and other waterborne pathogens might grow or spread to people so that a facility can reduce that risk. Moreover, #37 will assist in capturing the presence of a facility water management program and descriptive team members within the program. Finally, #38 will inform CDC of the process a facility uses to implement and monitor control measures, as well as corrective actions taken when a control limit is not met. These changes will increase the overall estimated burden of this form by 417 hours.
57.105	Group Contact Information	No change	No change	N/A
57.106	Patient Safety Monthly Reporting Plan	No change	No change	N/A
57.108	Primary Bloodstream Infection (BSI)	No change	New response options were added under Risk Factor section.	1) Added optional fields "Extracorporeal life support present (e.g. ECMO)" and "Ventricular assist device (VAD)" to further identify risk factors that can specifically be associated with BSI infection and potentially be excluded from CLABSI surveillance. Collection of this data will aide in analysis of BSI association with central lines. These changes will increase the overall estimated annual burden of this form by 13,200 hours.

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57.111	Pneumonia (PNEU)	No change	1) The number of reporting facilities were decreased by 4,200.	Reporting facilities were updated to reflect the actual number of facilities reporting into NHSN. This change will decrease the overall estimated burden for this form by 151,200 hours.
57.112	Ventilator-Associated Event	No change	2) Response option for VAE Risk Factor updated to change the response for "Airway Pressure Release Ventilation (APRV)" from required to optional.	1) Changed response for Airway Pressure Release Ventilation (APRV) Risk factor from required to optional. This field was originally requested to determine the frequency of the use of APRV mode. Adequate information have been gathered. These changes will increase the overall annual estimated burden of this form by 43,200 hours
57.113	Pediatric Ventilator- Associated Event (PedVAE)	No change	 New required response option "Gestational Age" was added under Risk Factor section. Response option Clinical event associated with the PedVAE added as an optional field. Response option "Antimicrobial agent(s) administered" added as an optional field. Response option "Pathogen identified from one or more of the listed specimens" added as an optional field. Response option "Pathogen identified from BLOOD" added as an optional field. The total number of respondents have decreased by 1,900. 	The NHSN PedVAE Form was developed amid increasing interest in the public health impact of conditions and complications in mechanically-ventilated neonates and children in acute care hospitals, long term acute care hospitals, and inpatient rehabilitation facilities. PedVAE surveillance will extend NHSN's current VAE surveillance to pediatric and neonatal populations (currently, VAE surveillance is only conducted in adult locations). PedVAE surveillance will provide a standardized, evidence-based surveillance method for identifying and tracking incidence and outcomes of ventilator-associated conditions in children in US healthcare facilities. These data may be used by facilities to identify areas where prevention and patient safety efforts may be improved. Additionally, Reporting facilities were updated to reflect the actual number of facilities reporting into NHSN. These changes will decrease the overall estimated burden of this form by 95,000 hours.
57.114	Urinary Tract Infection (UTI)	No change	1) Response options were updated to remove the "1" from "Event Criteria/Laboratory and Diagnostic Testing section".	1) UTI is primary site infection and cannot be secondary to another site of infection (USI exception). This change will eliminate redundancy and decrease confusion for facilities reporting on UTI. This change does not affect the estimated burden of this form.
57.115	Custom Event	No change	1) The total number of respondents have decreased by 1,400.	Reporting facilities were updated to reflect the actual number of facilities reporting into NHSN. This change will decrease the overall estimated burden for this form by 74,317 hours.

Form	Name	Name in	Itamizad Changes	Justifications
No.		last ICR	Itemized Changes	Justifications
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	 Increased the number responses per respondent from 9 to 12. Increased the burden per response from 3 to 4 burden hours for this form. Reporting of ventilator days for birth weight is conditionally required. Added PedVAE Optional Denominators for gestational age requesting optional PT, VNT, and EMV. 	 At a minimum neonatal units must perform CLABSI surveillance monthly. Burden was increased due to increased number of responses for CLABSI reporting. In addition, burden was increased to account for optional and conditionally required data collection for PedVAE. There is now a ventilator associated event available for NICU locations requiring related denominator reporting. There is now a ventilator associated event available for NICU locations requiring related denominator reporting, in which CDC has provided an option to accommodate facilities that are reporting requested data. These changes result in a net increase of 126,000 burden hours for this form.
57.117	Denominators for Specialty Care Area (SCA)/Oncology (ONC)	No change	Response options were updated from required to optional to collect APRV denominator days.	1) Changed response for Airway Pressure Release Ventilation (APRV) days from required to optional. This field was originally requested to determine the frequency of the use of APRV mode. Adequate information have been gathered. These changes will increase the overall annual estimated burden of this form by 1,080 hours
57.118	Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)	No change	Response options were updated from required to optional to collect APRV denominator days.	1) Changed response for Airway Pressure Release Ventilation (APRV) days from required to optional. This field was originally requested to determine the frequency of the use of APRV mode. Adequate information have been gathered. These changes will increase the overall annual estimated burden of this form by 7,200 hours.
57.120	Surgical Site Infection (SSI)	No change	No change	N/A
57.121	Denominator for Procedure	No change	No change	N/A
57.123	Antimicrobial Use and Resistance (AUR)- Microbiology Data Electronic Upload Specification Tables	No change	1) The total number of reporting facilities have decreased by 5,650.	1) The number of respondents was decreased from 6,000, which was a projected estimate, to 350 to account for the number of facilities using the NHSN Patient Safety Component for Antimicrobial Use and Resistance (AUR) data reporting, This change will decrease the overall estimated burden for this form by 5,650 hours.
57.124	Antimicrobial Use and Resistance (AUR)-	No change	The total number of respondents have	1) The number of respondents was decreased from 6,000, which was a

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Form No.		last ICR	Itemized Changes	Justifications
	Pharmacy Data Electronic Upload Specification Tables		decreased by 5,200.	projected estimate, to 800 to account for the number of facilities using the NHSN Patient Safety Component for Antimicrobial Use and Resistance (AUR)-Pharmacy data reporting. This change will decrease the overall estimated burden for this form by 5,200 hours.
57.125	Central Line Insertion Practices Adherence Monitoring	No change	1) The number of respondents was decreased from 1,000 to 100.	1) The number of respondents was decreased from 1,000 to 100 given that this form is optional and not required for Centers for Medicare and Medicaid Services (CMS) Quality Incentive Program (QIP). This change will result in a net decrease of 37,500 burden hours for this form.
57.126	MDRO or CDI Infection Form	No change	No change	N/A
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	No change	No change	N/A
57.128	Laboratory-identified MDRO or CDI Event	No change	No change	N/A
57.129	Adult Sepsis	No change	No change	N/A
57.137	Long-Term Care Facility Component – Annual Facility Survey	No change	 The number of respondents was increased to 2,600. Increased the burden per response from 1.08 to 2 burden hours for this form. Added optional Facility Water Management and Monitoring Program section #23, #24, and #25. 	 The number of respondents was increased from 350 to 2600 to account for the increase in LTCF facilities using the NHSN LTCF Component. Burden responses was increased to offset burden on facility responses for LTCF reporting. For question #23, a facility risk assessment is an import first step to identify areas where <i>Legionella</i> and other waterborne pathogens could grow and spread. The assessment may inform the water management program by identifying areas or devices in the building where <i>Legionella</i> and other waterborne pathogens might grow or spread to people so that a facility can reduce that risk. Moreover, #24 will assist in capturing the presence of a facility water management program and descriptive team members within the program. Finally, #25 will inform CDC of the process a facility uses to implement and monitor control measures, as well as corrective actions taken when a control limit is not met. These changes result in an increase of 4,822 burden hours for this form.
57.138	Laboratory-identified MDRO or CDI Event for	No change	The number of respondents was	1) The number of respondents was increased from 350 to 2600 to account

Form	Name	Name in	Itemized Changes	Justifications
No.	LTCF	last ICR	increased to 2,600. 2) Response options were updated to change the response for "Social Security Number" from required to optional.	for the increase in LTCF facilities using the NHSN LTCF Component. 2) Response for Social Security Number was changed from required to optional to minimize burden on users when the social security number is not available or the facility does not have that information. This change results in an increase of 9,350 burden hours for this form.
57.139	MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1) The number of respondents was increased to 2,600.	The number of respondents was increased from 350 to 2600 to account for the increase in LTCF facilities using the NHSN LTCF Component. This change will result in an increase of 4,500 burden hours for this form.
57.140	Urinary Tract Infection (UTI) for LTCF	No change	 The number of respondents was increased to 2,600. Response options were updated to change the response for "Social Security Number" from required to optional. Update wording on from under "lab/diagnostics" section. 	 The number of respondents was increased from 350 to 2600 to account for the increase in LTCF facilities using the NHSN LTCF Component. Response for Social Security Number was changed from required to optional to minimize burden on users when the social security number is not available or the facility does not have that information. Wording revised to add clarity for users completing form. This change result in an increase of 18,783 burden hours for this form.
57.141	Monthly Reporting Plan for LTCF	No change	1) The number of respondents was increased to 2,600.	The number of respondents was increased from 350 to 2600 to account for the increase in LTCF facilities using the NHSN LTCF Component. These changes result in an increase of 2,250 burden hours for this form.
57.142	Denominators for LTCF Locations	No change	 The number of respondents was increased to 2,600. Increased the burden per response from 3.35 to 4 burden hours for this form. 	 The number of respondents was increased from 350 to 2600 to account for the increase in LTCF facilities using the NHSN LTCF Component. Burden responses was increased to offset burden on facility responses for LTCF reporting. These changes result in an increase of 110,730 burden hours for this form.
57.143	Prevention Process Measures Monthly Monitoring for LTCF	No change	1) The number of respondents was increased to 2,600.	2) The number of respondents was increased from 250 to 300 to account for the increase in LTCF facilities using the NHSN LTCF Component. This change result in an increase of 2,300 burden hours for this form.
57.150	Patient Safety Component- Annual	No change	1) Added optional Facility Water Management and	1) For question #34, a facility risk assessment is an import first step to

Form	Name	Name in	Itemized Changes	Justifications
57.151	Facility Survey for LTAC Patient Safety Component-Annual Facility Survey for IRF	No change	Itemized Changes Monitoring Program section #34, #35, and #36.	identify areas where <i>Legionella</i> and other waterborne pathogens could grow and spread. The assessment may inform the water management program by identifying areas or devices in the building where <i>Legionella</i> and other waterborne pathogens might grow or spread to people so that a facility can reduce that risk. Moreover, #35 will assist in capturing the presence of a facility water management program and descriptive team members within the program. Finally, #36 will inform CDC of the process a facility uses to implement and monitor control measures, as well as corrective actions taken when a control limit is not met. These changes will increase the overall
57.200	Healthcare Personnel Safety Component	No change	No change	annual estimated burden of these forms by 116 hours. N/A
57.203	Annual Facility Survey Healthcare Personnel Safety Monthly Reporting Plan	No change	No change	N/A
57.204	Healthcare Worker Demographic Data	No change	No change	N/A
57.205	Exposure to Blood/Body Fluids	No change	No change	N/A
57.206	Healthcare Worker Prophylaxis/Treatment	No change	No change	N/A
57.207	Follow-Up Laboratory Testing	No change	No change	N/A
57.210	Healthcare Worker Prophylaxis/Treatment- Influenza	No change	No change	N/A
57.300	Hemovigilance Module Annual Survey – Acute Care Facility	Hemovigila nce Module Annual Survey	No Change	N/A
57.301	Hemovigilance Module Monthly Reporting Plan	No change	No change	N/A
57.303	Hemovigilance Module Monthly Reporting Denominators	No change	No change	N/A
57.304	Hemovigilance Adverse Reaction	No change	No change	N/A
57.305	Hemovigilance Incident	No change	No change	N/A
57.306	Hemovigilance Module Annual Survey - Non- Acute Care Facility	No change	No Change	N/A
57.307	Hemovigilance Adverse Reaction - Acute	No change	1) Response options were updated to change the	Based on user feedback CDC has decided to change required fields for

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
140.	Hemolytic Transfusion Reaction	lastick	response for "Medical history", "Transfusion history", and "Patient treatment history" from required to optional for forms 57.307-57.320. 2) Updated response options in the Patient Treatment Section. 3) Burden per responses for forms 57.307-57.320 will decrease from 25 minutes to 20 minutes for each form.	Medical history, Transfusion history, and Patient treatment to optional. This will reduce the burden of hours it takes for facilities to report non-acute adverse reactions for forms 57.307- 57.320. 2) Added 'Unknown' as a category under the Patient Treatment Section of the Biovigilance Adverse Reaction Event. This will eliminate recall bias for facilities. 3) Changing required fields to optional will provide reporting facilitates the flexibility to report on outcomes that best fit their patient populations and reporting need for NHSN. These changes result in a decrease of 667
57.308	Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	No change		burden hours for this form. These changes result in a decrease of 667 burden hours for this form.
57.309	Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	No change		These changes result in a decrease of 167 burden hours for this form.
57.310	Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	No change		These changes result in a decrease of 333 burden hours for this form.
57.311	Hemovigilance Adverse Reaction - Febrile Non- hemolytic Transfusion Reaction	No change		These changes result in a decrease of 667 burden hours for this form.
57.312	Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	No change		These changes result in a decrease of 167 burden hours for this form.
57.313	Hemovigilance Adverse Reaction - Infection	No change		This change result in a decrease of 167 burden hours for this form.
57.314	Hemovigilance Adverse Reaction - Post Transfusion Purpura	No change		These changes result in a decrease of 167 burden hours for this form.
57.315	Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	No change		These changes result in a decrease of 167 burden hours for this form.
57.316	Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	No change		These changes result in a decrease of 167 burden hours for this form.
57.317	Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	No change		These changes result in a decrease of 167 burden hours for this form.
57.318	Hemovigilance Adverse Reaction - Transfusion Associated Circulatory	No change		These changes result in a decrease of 333 burden hours for this form.

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57.319 57.320	Overload Hemovigilance Adverse Reaction - Unknown Transfusion Reaction Hemovigilance Adverse	No change No change		These changes result in a decrease of 167 burden hours for this form.
	Reaction - Other Transfusion Reaction			These changes result in a decrease of 167 burden hours for this form.
57.400	Outpatient Procedure Component—Annual Facility Survey	No change	 Revised response option under "Facility Characteristics". Removed reference to "HOPD". 	 Added response which will allow ASC to report current CMS accreditation status. Due to limited reporting for only ASCs this is no longer necessary to complete. These changes will increase the overall annual estimated burden of this form by 417 hours.
57.401	Outpatient Procedure Component - Monthly Reporting Plan	No change	Created new section on form. Revised SSI Surveillance section.	 Created new section titled "Antibiotic timing" for clarity for users. Modified this section to allow more flexibility in using the form. These changes will increase the overall annual estimated burden of this form by 5,000 hours.
57,402	Outpatient Procedure Component Same Day Outcome Measures	Outpatient Procedure Component Event	 Revised name of the form. Removed "SSI" Section. Removed "Antibiotic Timing section" Decreased the number of respondents by 3,800. 	 Add clarity for events being reported Separated items in this section to developed a more detailed event form, which is a new form (57.405) Ensure that OPC aligns with the CMS ASC reporting requirements The number of respondents was decreased from 5,000, which was a projected estimate, to 1,200 to account for the number of facilities using the NHSN OPC SSI data reporting. These changes will decrease the estimated burden hours for this form by 63,333 hours.
57.403	Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	Outpatient Procedure Component - Monthly Denominato rs and Summary	 Revised the name of form. Removed "SSI" Section. Removed "Antibiotic Timing section" Decreased the number of respondents by 3,800. 	 Add clarity for denominators being reported Separated items in this section to developed a more detailed event form, which is a new form (57.404) Ensure that OPC aligns with the CMS ASC reporting requirements The number of respondents was decreased from 5,000, which was a projected estimate, to 1,200 to account for the number of facilities using the NHSN OPC SSI data reporting. These changes will decrease the estimated burden hours for this form by 30,400 hours.
57.404 57.405	Outpatient Procedure Component – SSI Denominators Outpatient Procedure Component - Surgical	N/A. These are new forms.	New forms are being added as part of the NHSN Outpatient Procedure Component.	1) The revised OPC Event form (57.402) split into two separate event specific forms to add clarity for users. Splitting the form prevents facilities from reading through questions that do not pertain to

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	Site (SSI) Event			the event type that is being reported. These new form add an additional 555,000
57.500	Outpatient Dialysis Center Practices Survey	No change	1) Increase in the number of respondents from 6,500 to 7,000. 2) Added question #2B 3) Modified section header for section A3. 4) Added question #16 and #17. 5) Added question #20. 6) Modify response options for question #34. 7) Added question #43b and #44. 8) Modify response options modified for #51, #57, and #61. 10) Added question #62 A&B.	burden hours to this ICR. 1) The increase in the facilities is due to an increase in dialysis facility enrollment and projected growth of the dialysis component. 2) Question added to estimate the prevalence of outpatient dialysis centers that are associated with a teaching hospitals. 3) Modified section to "Patient Records and Surveillance" to better reflect the information captured in this section. 4) These questions have been added to align with the Home Dialysis Center Practices Survey and to provide consistency between both surveys. Questions #16 & #17 will estimate national prevalence for surveillance infections in both peritoneal and home hemodialysis patients. 5) Question added to estimate the national prevalence of AKI patients in outpatient hemodialysis centers. 6) Question modified "blood" to "patient blood culture" for clarification and deleting the option "water" because it is no longer applicable to this question. These modifications will accurately determine information on national practices about testing following pyrogenic reactions. 7) Question #43b will evaluate the Making Dialysis Safer for Patients Coalition and its impact for prevention of bloodstream infections. Question #44 was added for the purposes of evaluating how nephrologist engage in prevention and educational activities, which can inform best practices for reducing bloodstream infections and help measure the impact of such activities 8) Removed answer choice "N/A" because NHSN has business in place to enforce yes/no option in the future. 9) Modified answer choices for question #51 due to reports that data showed many facilities documented "other, specify"; adding "antiseptic wipes" as a choice helps to accurately evaluate national sterilization practices. For question #57 and #61 responses were revised to reflect "n/a-chlorhexidine-

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No.		last ICR		impregnated dressing is routinely used" to nationally estimate the different types of exit site practices used during dressing change for hemodialysis catheters. For #61 response options updated to reflect the different trade names used for this particular catheter care treatment to help facilities select best option. 10) Questions added to evaluate the care for hemodialysis catheter patients, which can inform risk factors for bloodstream infections outside the center. These changes result in an increase of 1,350
57.501	Dialysis Monthly Reporting Plan	No change	 Increase in the number of respondents from 6,500 to 7,000. Added new field to form. 	 burden hours for this form. The increase in the facilities is due to an increase in dialysis facility enrollment and projected growth of the dialysis component. Added a new comment box. Due to a large request from Large Dialysis Organizations (LDOs) to add a comment box to the Dialysis Monthly Reporting Plan. LDOs would like a way to document additional information for certain plan selections, such as "Not Participating in NHSN". These changes result in an increase of 500 burden hours for this form.
57.502	Dialysis Event	No change	 Increase in the number of respondents from 6,500 to 7,000. Modified question in "Event Details". 	 The increase in the facilities is due to an increase in dialysis facility enrollment and projected growth of the dialysis component. Required question modified to accurately and consistently estimate national prevalence of IV antimicrobial starts. These changes result in an increase of 12,500 burden hours for this form.
57.503	Denominators for Dialysis Event Surveillance	No change	 Increase in the number of respondents from 6,500 to 7,000. Modified formatting. 	 The increase in the facilities is due to an increase in dialysis facility enrollment and projected growth of the dialysis component. Changed asterisk (*) placement on form to provide consistency with the NHSN user interface. These changes result in an increase of 1,000 burden hours for this form.
57.504	Prevention Process Measures Monthly Monitoring for Dialysis	No change	1) Increase in the number of respondents from 1,500 to 2,000.	The increase in the facilities is due to an increase in dialysis facility enrollment and projected growth of the dialysis component. These changes result in an increase of 7,500 burden hours for this form.
57.505	Dialysis Patient	No change	No Change	N/A
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	Influenza Vaccination			
57.506	Dialysis Patient Influenza Vaccination Denominator	No change	No Change	N/A
57.507	Home Dialysis Center Practices Survey	No change	 Decrease in the number of respondents from 600 to 350. Decrease burden of completing form by 10 minutes. Added questions #16 and #17. Modified response options for #18. Modified Response option for #20. Modified Response option for #22. Modified question #23 and #24. Modified response options for question #28. Modified question #31. 	 The decrease in the number of respondents is to accurately reflect current use and projected estimates of home dialysis facilities in NHSN. Response options have been updated to decrease the burden on facilities, which resulted in a decrease of 10 minutes in burden to complete this form. Question #16 will evaluate the Making Dialysis Safer for Patients Coalition and its impact for prevention of bloodstream infections. Question #17 will evaluate how nephrologist engage in prevention and educational activities, which can inform best practices for reducing bloodstream infections and help measure the impact of such activities. Removed answer choice "N/A" because NHSN has business in place to enforce yes/no option in the future. Clarified response option to help accurately evaluate national sterilization practices. Updated response by removing "n/a, no fistula patient's" to provide consistency with the outpatient dialysis center practice survey and to provide clarification given this choice is no longer applicable for this patient population. Questions updated to provide clarification and consistency for users to estimate national practices of antimicrobial ointments used on buttonhole cannulation to prevent infections. Response options updated to nationally estimate the different types of exit site practices used during dressing change for hemodialysis catheters. Updated question to clarify which practices are frequently used to estimate national practices for catheter care, and modified responses to reflect the different trade names used for this particular catheter care treatment to help facilities select best option. These changes result in a decrease of 75 burden hours for this form.