

### 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 include section for the new Antimicrobial Use and Resistance Component.	1) The form was updated to include applicable sections for the new Antimicrobial Use and Resistance Component. This change does not affect the estimated burden of this form.
57.103	Patient Safety Component-Annual Hospital Survey	No change	1) Revision of questions within the Facility Microbiology Laboratory Practices section. 2) Addition of new section for Infection Control Practices. 3) Addition of new section for Antibiotic Stewardship Practices.	1) The Facility Microbiology Laboratory Practices section of the survey was reviewed by internal laboratory experts and it was determined that some questions were no longer needed as the majority of laboratories are following similar practices to adhere to industry guidelines. Response options were also added to be inclusive of all laboratory types used by healthcare facilities. A few questions were added to obtain information regarding activities to prevent furthering of antimicrobial resistance within the individual healthcare facility. 2) Questions about infection control practices have been added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms. 3) Questions about antibiotic stewardship have been added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals. These changes result in an increase of 2,000 burden hours for this form.

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.105	Group Contact Information	No change	1) Decrease the total number of respondents from 6,000 to 1,000.	1) After reviewing the use of this form, it was determined that there are far fewer respondents using this form than originally estimated; therefore, the total number of respondents has been decreased to 1,000 per year. This change results in a decrease of 417 burden hours.
57.106	Patient Safety Monthly Reporting Plan	No change	1) Remove Patient Vaccination section of the reporting plan.	1) Due to low use of the Patient Vaccination Module, it will be removed from NHSN and therefore removed from the Monthly Reporting Plan. Additionally, the form's estimated time to completion was assessed and determined to be less than originally projected. The removal of the Patent Vaccination Module from the form along with the reduced time to completion decreases the total burden of this form by 24,000 burden hours.
57.108	Primary Bloodstream Infection (BSI)	No change	1) Revision of susceptibility options for Cefepime. 2) Criteria clarification for neutropenia. 3) Increase number of responses from 36 to 44.	1) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms. 2) Clarification was added to the form for the underlying condition of neutropenia to assist users in making this determination. 3) In 2015, CMS will be requiring all acute care facilities participating in the IQR Program to report BSIs from medical, surgical, and medical/surgical wards within their facilities. Therefore, the estimated number of times this form will be completed per facility has been increased from 36 times to 44 times per year. Additionally, the form's estimated time to completion was assessed and determined to be less than originally projected. These combined changes result in an increase of 16,800 burden hours for this form.

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.111	Pneumonia (PNEU)	No change	<ol style="list-style-type: none"> <li>1) A number of revisions were made related to modifications of the PNEU/VAP protocol and reflect simplifications and clarifications to more accurately reference laboratory testing methodology.</li> <li>2) Revision of susceptibility options for Cefepime.</li> </ol>	<ol style="list-style-type: none"> <li>1) As consistent with all other HAI infection definition revisions, non-culture laboratory testing results used to meet the PNEU definition are now group together as one selection and referred to as <i>Positive non-culture diagnostic test of respiratory secretions or tissue</i>. For clarification purposes, delineation between histopathologic exam test results and culture test results was provided. To that end <i>Positive quantitative culture of lung parenchyma</i> is no longer grouped within the former selection <i>Histopathologic exam w/ abscess formation, positive quantitative culture of lung parenchyma, or lung parenchyma invasion by fungal hyphae</i>. It is now a separate selection. <i>Pneumocystis carinii</i> was deleted from the selection: <i>Fungi or Pneumocystis carinii from LRT specimen</i> as this reflects a change to the PNEU/VAP protocol whereby this is now an excluded pathogen for meeting the PNEU definition.</li> <li>2) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: <i>Escherichia coli</i>, <i>Enterobacter</i>, and <i>Klebsiella</i>. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms.</li> </ol> <p>These changes result in an increase of 7,200 burden hours for this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.112	Ventilator-Associated Event	No change	<ol style="list-style-type: none"> <li>1) Possible VAP and Probable VAP (third tier of VAE definition algorithm) were consolidated to create one specific event: PVAP.</li> <li>2) Revision of susceptibility options for Cefepime.</li> </ol>	<ol style="list-style-type: none"> <li>1) Possible VAP and Probable VAP (third tier of VAE definition algorithm) were consolidated to create one specific event: PVAP. Facilities have different approaches to processing and reporting Gram stain and culture data. Having two separate specific events within the tier (possible and probable) made it difficult to have an objective definition. Combining the two specific events into one specific event will simplify the VAE definition algorithm and is additionally consistent with how analysis would likely be done (combining possible VAP and Probable VAP to arrive at a third tier rate).</li> <li>2) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms.</li> </ol> <p>These changes result in an increase of 43,200 burden hours for this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.114	Urinary Tract Infection (UTI)	No change	<ol style="list-style-type: none"> <li>1) Addition of new fields.</li> <li>2) Addition of the neutropenia criteria.</li> <li>3) Removal of dysuria from criteria for children less than 1 year old.</li> <li>4) Revision of specific event type from OUTI to USI.</li> <li>5) Revision of susceptibility options for Cefepime.</li> <li>6) Estimated number of responses per respondent was increased from 27 to 40.</li> </ol>	<ol style="list-style-type: none"> <li>1) These fields (purulence around catheter and acute pain, swelling or tenderness of the epididymis, testes and prostate) will provide greater sensitivity in identifying catheter-associated UTIs that may not have been identified with previous CAUTI definitions.</li> <li>2) The addition of the neutropenia criteria will allow us to be more specific in identifying UTIs. Immunocompromised patients may not be able to produce WBCs in response to infection and the addition of this information allows us to analyze data more appropriately.</li> <li>3) Dysuria was removed based on input from our pediatrician on staff. Patients under 1 year of age are very unlikely to express dysuria so it is not useful for diagnosing UTI in that population.</li> <li>4) OUTI was changed to USI to clarify that it did not involve a urine culture and should be considered separately from OUTI. It also allows for more clear delineation of infections of the urinary system that occur as a result of surgical procedures.</li> <li>5) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms.</li> <li>6) In 2015, CMS will be requiring all acute care facilities participating in the IQR Program to report UTIs from medical, surgical, and medical/surgical wards within their facilities. Therefore, the estimated number of times this form will be completed per facility has been increased from 27 times to 40 times per year.</li> </ol> <p>These changes result in an increase of 41,700 burden hours for this form.</p>
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	No changes	N/A

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.117	Denominators for Specialty Care Area (SCA)/Oncology (ONC)	No change	1) Add field to capture episodes of mechanical ventilation.	1) Episodes of Mechanical Ventilation (EMV) was added as an optional denominator. Decreasing the number of ventilator days is an intervention aimed at reducing ventilator related event rates. However, if the ventilator denominator is decreased it is possible that the rate will not improve and could possibly increase. The introduction of EMV as a denominator is being introduced as an alternative means of evaluating VAE rates. This change does not affect the estimated burden of this form.
57.118	Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)	No change	1) Add field to capture episodes of mechanical ventilation.	1) Episodes of Mechanical Ventilation (EMV) was added as an optional denominator. Decreasing the number of ventilator days is an intervention aimed at reducing ventilator related event rates. However, if the ventilator denominator is decreased it is possible that the rate will not improve and could possibly increase. The introduction of EMV as a denominator is being introduced as an alternative means of evaluating VAE rates. This change does not affect the estimated burden of this form.
57.120	Surgical Site Infection (SSI)	No change	1) Add question to assess whether infection was present at the time of surgery (PATOS). 2) Remove question to identify whether the SSI was detected using the NHSN ICD Code-based Admit and Readmit SSI Surveillance Toolkit. 3) Revision of susceptibility options for Cefepime. 4) Revision of criteria for signs and symptoms of SSI.	1) Adding this question will allow NHSN to do analysis based on SSIs that occur when there was an infection present at the time of the surgery. 2) This question was removed from the form as CDC DHQP leadership felt that this feed was too complicated for users to complete. 3) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. However, because not all laboratories will implement this change at the same time, the susceptibility options for Cefepime for those three organisms will include both I and S-DD on all NHSN event forms. 4) In order to be consistent throughout NHSN definitions, SSI signs and symptoms criteria were amended. These changes result in a net increase of 21,600 burden hours for this form.

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.121	Denominator for Procedure	No change	1) Add question to assess whether the total or partial knee/hip revision was associated with prior infection at the index joint.	1) This question was based on the decisions/discussion of the SSI Healthcare Infection Control Practices Advisory Committee (HICPAC) workgroup. These revisions will have a much higher SSI rate and adding this field will enable better future risk adjusted data analysis. This change does not affect the estimated burden of this form.
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	No changes	N/A
57.125	Central Line Insertion Practices Adherence Monitoring	No change	No changes	N/A
57.126	MDRO or CDI Infection Form	No change	<ol style="list-style-type: none"> <li>1) Revision of criteria for signs and symptoms and laboratory or diagnostic testing of MDRO or CDI infection event.</li> <li>2) Add CRE-<i>Enterobacter</i> as a specific organism type.</li> <li>3) Revision of susceptibility options for Cefepime.</li> </ol>	<ol style="list-style-type: none"> <li>1) In order to be consistent and remove duplication throughout NHSN definitions, MDRO or CDI signs and symptoms and laboratory or diagnostic criteria were amended.</li> <li>2) CRE-<i>Enterobacter</i> added as an option for specific organism type to accommodate an additional organism and definition change in the MDRO protocols for LabID Event and Infection Surveillance reporting.</li> <li>3) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: <i>Escherichia coli</i>, <i>Enterobacter</i>, and <i>Klebsiella</i>. Therefore the susceptibility options for Cefepime for those three organisms should be changed from S, I, R, N to S, S-DD, R, N on all NHSN event forms. This change results in an increase of 7,200 burden hours for this form.</li> </ol>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	No change	<ol style="list-style-type: none"> <li>1) Add question to obtain denominator counts for total facility excluding units with unique CMS Certification Numbers (CCNs).</li> <li>2) Add CRE-<i>Enterobacter</i> as a specific organism type.</li> </ol>	<ol style="list-style-type: none"> <li>1) FacWideIN reporting for acute care will include locations with the same CMS Certification Number (CCN) only. Unique CCN's will be removed from FacWideIN counts. This change is in alignment with current and future CMS reporting rules for participating facilities.</li> <li>2) CRE-<i>Enterobacter</i> added as an option for specific organism type to accommodate an additional organism and definition change in the MDRO protocols for LabID Event and Infection Surveillance reporting.</li> </ol> <p>These changes result in the addition of 7,200 burden hours to this form.</p>
57.128	Laboratory-identified MDRO or CDI Event	No change	<ol style="list-style-type: none"> <li>1) Add CRE-<i>Enterobacter</i> as a specific organism type.</li> <li>2) Add new question to determine last physical overnight location of patient immediately prior to arriving into facility.</li> <li>3) Add new question to determine whether patient has been discharged from another facility in the past 4 weeks.</li> </ol>	<ol style="list-style-type: none"> <li>1) CRE-<i>Enterobacter</i> added as a specific organism type to accommodate an additional organism and definition change in the MDRO protocols for LabID Event and Infection Surveillance reporting.</li> <li>2) Last physical overnight location of patient immediately prior to arriving into facility (applies to specimen collected in outpatient setting or &lt;4 days after inpatient admission was added to enable continuum of care and compliment community onset data collected by Emerging Infections Program by allowing users to track referral sources.</li> <li>3) Has patient been discharged from another facility in the past 4 weeks was added to enable continuum of care and enable facilities to track time spent in other healthcare facilities.</li> </ol> <p>These changes do not affect the estimated burden of this form.</p>
57.130	Vaccination Monthly Monitoring Form-Summary Method	No change	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN.</li> </ol>	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN. Removing this form results in decreasing the total package burden by 7,000 burden hours.</li> </ol>
57.131	Vaccination Monthly Monitoring Form-Patient-Level Method	No change	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN.</li> </ol>	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN. Removing this form results in decreasing the total package burden by 1,000 burden hours.</li> </ol>
57.133	Patient Vaccination	No change	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN.</li> </ol>	<ol style="list-style-type: none"> <li>1) This form will be removed from the package as the Patient Vaccination Module will be removed from NHSN. Removing this form results in decreasing the total package burden by 4,167 burden hours.</li> </ol>



Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.137	Long-Term Care Facility Component – Annual Facility Survey	No change	1) Addition of new section for Infection Control Practices. 2) Addition of new section for Antibiotic Stewardship Practices.	1) Questions about infection control practices have been added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms. 2) Questions about antibiotic stewardship have been added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals. These changes result in an increase of 63 burden hours for this form.
57.138	Laboratory-identified MDRO or CDI Event for LTCF	No change	1) Add CRE- <i>Enterobacter</i> as a specific organism type.	1) CRE- <i>Enterobacter</i> added as a specific organism type to accommodate an additional organism and definition change in the MDRO protocols for LabID Event and Infection Surveillance reporting. This change does not affect the estimated burden of this form.
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	No change	1) Add CRE- <i>Enterobacter</i> as a specific organism type.	1) CRE- <i>Enterobacter</i> added as a specific organism type to accommodate an additional organism and definition change in the MDRO protocols for LabID Event and Infection Surveillance reporting. This change does not affect the estimated burden of this form.

<b>Form No.</b>	<b>Name</b>	<b>Name in last ICR</b>	<b>Itemized Changes</b>	<b>Justifications</b>
57.140	Urinary Tract Infection (UTI) for LTCF	No change	<ol style="list-style-type: none"> <li>1) Revision of susceptibility options for Cefepime.</li> <li>2) Average time to complete form was increased to 30 minutes.</li> </ol>	<ol style="list-style-type: none"> <li>1) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. Therefore the susceptibility options for Cefepime for those three organisms should be changed from S, I, R, N to S, S-DD, R, N on all NHSN event forms.</li> <li>2) After reevaluating the form, it was determined that the average time to complete the form should be increased from 27 minutes to 30 minutes per response.</li> </ol> <p>These changes result in an increase of 113 burden hours for this form.</p>
57.141	Monthly Reporting Plan for LTCF	No change	No changes	N/A
57.142	Denominators for LTCF Locations	No change	<ol style="list-style-type: none"> <li>1) Addition of a question: "New antibiotic starts for UTI indication."</li> <li>2) Addition of a question: "Number of admissions on C. difficile treatment."</li> </ol>	<ol style="list-style-type: none"> <li>1) This column is being added to enable nursing home providers to capture antibiotic starts for UTI indications for all residents in the facility on a monthly basis. Facilities can track these new antibiotic starts on a daily basis or provide a total number at the end of each month. This summary measure will provide additional context for the interpretation of their UTI event data and may help identify opportunities for quality improvement when reported UTI surveillance events are much lower than clinically treated UTI events.</li> <li>2) This column is being added to enable nursing home providers to capture residents receiving antibiotic treatment for C.difficile infection at the time of admission to their facility on a monthly basis. A growing body of evidence shows that a healthcare facility's C.difficile infection rates can be strongly impacted by the importation of C.difficile from people actively or recently infected at the time of admission. By collecting data on the prevalence of C.difficile treatment on admission, facilities will have a proxy measure of this importation factor which can be used to interpret their C.difficile infection rates.</li> </ol> <p>These changes result in an increase of 750 burden hours for this form.</p>
57.143	Prevention Process Measures Monthly Monitoring for LTCF	No change	No changes	N/A

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.150	Patient Safety Component- Annual Facility Survey for LTAC	No change	<ol style="list-style-type: none"> <li>1) Addition of a new question to obtain number of admissions of patients with certain conditions.</li> <li>2) Revision of questions within the Facility Microbiology Laboratory Practices section.</li> <li>3) Addition of new section for Infection Control Practices.</li> <li>4) Addition of new section for Antibiotic Stewardship Practices.</li> </ol>	<ol style="list-style-type: none"> <li>1) A new question was added to the survey to obtain the number of admissions of patients with certain conditions. These data will assist in providing accurate risk adjustment of LTAC facility metrics.</li> <li>2) The Facility Microbiology Laboratory Practices section of the survey was reviewed by internal laboratory experts and it was determined that some questions were no longer needed as the majority of laboratories are following similar practices to adhere to industry guidelines. Response options were also added to be inclusive of all laboratory types used by healthcare facilities. A few questions were added to obtain information regarding activities to prevent furthering of antimicrobial resistance within the individual healthcare facility.</li> <li>3) Questions about infection control practices have been added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms.</li> <li>4) Questions about antibiotic stewardship have been added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals.</li> </ol> <p>These changes result in an increase of 133 burden hours for this form.</p>

<b>Form No.</b>	<b>Name</b>	<b>Name in last ICR</b>	<b>Itemized Changes</b>	<b>Justifications</b>
57.151	Patient Safety Component-Annual Facility Survey for IRF	No change	<ol style="list-style-type: none"> <li>1) Revision of questions within the Facility Microbiology Laboratory Practices section.</li> <li>2) Addition of new section for Infection Control Practices.</li> <li>3) Addition of new section for Antibiotic Stewardship Practices.</li> </ol>	<ol style="list-style-type: none"> <li>1) The Facility Microbiology Laboratory Practices section of the survey was reviewed by internal laboratory experts and it was determined that some questions were no longer needed as the majority of laboratories are following similar practices to adhere to industry guidelines. Response options were also added to be inclusive of all laboratory types used by healthcare facilities. A few questions were added to obtain information regarding activities to prevent furthering of antimicrobial resistance within the individual healthcare facility.</li> <li>2) Questions about infection control practices have been added to the survey for the purpose of gaining a better understanding of current practices and to identify areas to target prevention efforts among facilities that have reported a multidrug-resistant organism. The information collected will inform future efforts to improve facility implementation of recommended prevention measures to control spread of multidrug-resistant organisms.</li> <li>3) Questions about antibiotic stewardship have been added to the survey for the purpose of gaining a better understanding of current efforts to improve antibiotic use in hospitals and to assess the quality of hospital antibiotic stewardship programs. The information collected will inform efforts to improve facility implementation of best practices to improve antibiotic stewardship programs and antibiotic use in hospitals.</li> </ol> <p>These changes result in an increase of 417 burden hours for this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.154	Antimicrobial Use & Resistance Component - Monthly Reporting Plan	N/A. This is a new form	A new form is being added as part of the new NHSN Antimicrobial Use and Resistance Component.	A new component will be launched within NHSN that will specifically examine antimicrobial use (AU) and antimicrobial resistance (AR) within healthcare facilities: Antimicrobial Use and Resistance (AUR) Component. The goal of the AUR Component is to provide a mechanism for facilities to report and analyze antimicrobial use and/or resistance as part of local or regional efforts to reduce antimicrobial resistant infections through antimicrobial stewardship efforts or interruption of transmission of resistant pathogens at their facility. AU and AR functionalities currently exist within NHSN but participation is limited to inpatient healthcare facilities. Moving the AU and AR Modules to a separate NHSN Component will allow all healthcare facility types, such as outpatient dialysis facilities and long-term care facilities, to take advantage of these tools for antimicrobial stewardship. This new form will add a total of 100 burden hours to the ICR.
57.200	Healthcare Personnel Safety Component Annual Facility Survey	No change	No changes	N/A
57.203	Healthcare Personnel Safety Monthly Reporting Plan	No change	<ol style="list-style-type: none"> <li>1) New response options were added to this form: 'influenza vaccination summary for the hospital' and 'influenza vaccination summary for the inpatient rehabilitation facility unit(s).'</li> <li>2) Number of respondents increased from 50 to 11,000.</li> <li>3) Number of responses per respondent decreased from 9 to 1.</li> </ol>	<ol style="list-style-type: none"> <li>1) These response options were added to allow facilities to separate the reporting of influenza vaccination summary data from the hospital units versus the inpatient rehabilitation facility units for CMS reporting purposes.</li> <li>2) Due to an increase in CMS required reporting of influenza vaccination summary data, this form must be completed by all acute care facilities, inpatient rehabilitation facilities, long term acute care facilities, and ambulatory surgical centers participating in CMS reporting programs. Therefore, the number of respondents using this form has been increased to 11,000.</li> <li>3) Recent updates within NHSN have allowed the monthly reporting plan to be auto-populated after one month has been entered. Therefore, facilities are now only required to submit this form once per year and NHSN will automatically complete the remaining months' reporting plans.</li> </ol> <p>These changes result in a net increase of 842 burden hours for this form.</p>
57.204	Healthcare Worker Demographic Data	No change	No changes	N/A

<b>Form No.</b>	<b>Name</b>	<b>Name in last ICR</b>	<b>Itemized Changes</b>	<b>Justifications</b>
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	No changes	N/A
57.301	Hemovigilance Module Monthly Reporting Plan	No change	No changes	N/A
57.303	Hemovigilance Module Monthly Reporting Denominators	No change	No changes	N/A
57.304	Hemovigilance Adverse Reaction	No change	No changes	N/A
57.305	Hemovigilance Incident	No change	<ol style="list-style-type: none"> <li>1) Order of the questions was revised on the form.</li> <li>2) Number of responses per respondent decreased from 12 to 10 per year.</li> </ol>	<ol style="list-style-type: none"> <li>1) The order was changed to streamline the data collection process for the facilities.</li> <li>2) The form now accommodates the addition of up to 20 incident codes and locations per form. This change allows facilities to now report all the incidents that were associated with an adverse reaction on a single form instead of completing a new form for every single incident. This change reduces the burden on facilities because they will no longer need to complete separate forms in these situations.</li> </ol> <p>These changes result in a net decrease of 167 burden hours for this form.</p>
57.400	Outpatient Procedure Component—Annual Facility Survey	No change	No changes	N/A
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

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.500	Outpatient Dialysis Center Practices Survey	No change	<ol style="list-style-type: none"> <li>1) Add question for CMS End Stage Renal Disease (ESRD) Network number and name.</li> <li>2) Add answer response for question #7.</li> <li>3) Add a question to assess influenza vaccination status.</li> <li>4) Add question to assess hepatitis B vaccination of home hemodialysis patients.</li> <li>5) Update response options for question #38.</li> <li>6) Revisions of question and response wording.</li> <li>7) Increase total respondents from 6,000 to 6,500.</li> </ol>	<ol style="list-style-type: none"> <li>1) Adding variable for ESRD patient advocacy network # and network name in order to clearly identify the facility's network.</li> <li>2) Adding "Patient Care Technician" as response option to gather more detailed information regarding all potential parties that could be involved in infection control practices within the facility.</li> <li>3) Adding the question "19c. Of your center's MAINTENANCE, NON-TRANSIENT, in-center hemodialysis patients from question 17a, how many received the influenza vaccine for the current/most recent flu season?"</li> <li>4) Adding the question, "20a. Of your center's MAINTENANCE, NON-TRANSIENT, home hemodialysis patients from question 17b, how many received at least 3 doses of hepatitis B vaccine ever?" in order to distinguish the number of home hemodialysis patients that received the vaccine only.</li> <li>5) Update response categories to include "Yes-all," "Yes-some, No-None" because want to examine how many facilities are using none, some, or all nine of the CDC-recommended Core interventions.</li> <li>6) After internal and external review, many of the questions and response options have been edited for clarification purposes.</li> <li>7) Increased number of facilities from 6,000 to 6,500 to accommodate the growing number of dialysis facilities anticipated over the next 3 years.</li> </ol> <p>These changes result in a net increase of 875 burden hours for this form.</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.501	Dialysis Monthly Reporting Plan	No change	<ol style="list-style-type: none"> <li>1) Add new fields for prevention process measures and patient vaccination.</li> <li>2) Increase total respondents from 6,000 to 6,500.</li> </ol>	<ol style="list-style-type: none"> <li>1) Adding the following sections for facilities to begin reporting on: HD Catheter Connection/Disconnection, HD Catheter Exit Site Care, AV Fistula &amp; Graft Cannulation/Decannulation, Dialysis Station Routine Disinfection, and Injection Safety. Adding “Influenza Vaccination – Dialysis Patients” under the new “Patient Vaccination” field so that facilities can begin tracking patient vaccination events.</li> <li>2) Increased number of facilities from 6,000 to 6,500 to accommodate the growing number of dialysis facilities anticipated over the next 3 years.</li> </ol> <p>These changes result in a net increase of 900 burden hours for this form.</p>
57.502	Dialysis Event	No change	<ol style="list-style-type: none"> <li>1) Add question “suspected source of positive blood culture.”</li> <li>2) Rewording of two form elements.</li> <li>3) Revision of susceptibility options for Cefepime.</li> <li>4) Increase number of annual respondents from 6,000 to 6,500.</li> </ol>	<ol style="list-style-type: none"> <li>1) The question “Where was this positive blood culture collected?” was added to determine how well facilities are able to follow-up on positive blood culture results produced outside their facility.</li> <li>2) Based on analysis, we observed that non-vascular accesses were erroneously included in reporting. Therefore, we are rewording the response to “Other vascular access device,” in order to specify vascular access types only and improve data quality. Users also erroneously reported non-vascular accesses. Therefore, modifying answer option to “Other vascular access device” in order to specify vascular access types only and improve data quality.</li> <li>3) Recently CLSI has updated the susceptibility options for Cefepime to replace Intermediate (I) with Susceptible-dose dependent (S-DD) for three organisms: Escherichia coli, Enterobacter, and Klebsiella. Therefore the susceptibility options for Cefepime for those three organisms should be changed from S, I, R, N to S, S-DD, R, N on all NHSN event forms.</li> <li>4) Increased number of facilities from 6,000 to 6,500 to accommodate the growing number of dialysis facilities anticipated over the next 3 years.</li> </ol> <p>These changes result in a net increase of 52,000 burden hours for this form.</p>



Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.503	Denominators for Dialysis Event Surveillance	Denominator for Outpatient Dialysis	1) Change in form title. 2) Removal of 'maintenance' from form. 3) Wording added for clarification. 4) Increase number of annual respondents from 6,000 to 6,500.	1) The title of the form has been changed from "Denominators for Outpatient Dialysis" to "Denominators for Dialysis Event Surveillance" in order to clarify that this form is specific to dialysis event surveillance only and not applicable to other surveillance options that are available under the new Dialysis component. 2) Changing verbiage of "maintenance hemodialysis patients"/"maintenance hemodialysis" to "hemodialysis outpatients"/"hemodialysis" to prevent the inadvertent exclusion of acute care hemodialysis patients, thereby improving data quality. 3) Changing verbiage of the column header from "Patients" to "Outpatients" to clarify that inpatients being treated at the same facility should be excluded. The text has been modified to "Other vascular access device (e.g., catheter-graft hybrid, port)" for clarification and consistency between all dialysis forms. 4) Increased number of facilities from 6,000 to 6,500 to accommodate the growing number of dialysis facilities anticipated over the next 3 years. These changes result in a net increase of 600 burden hours for this form.
57.504	Prevention Process Measures Monthly Monitoring for Dialysis	No change	1) Add new fields to capture new variables. 2) Increase number of annual respondents from 600 to 1,500.	1) Added five new process measures that can significantly play a role in improving adherence to best practices, thereby reducing infection. Each additional measure dovetails the CDC-recommended audit tools and they are as follows: Hemodialysis Catheter Connection/Disconnection, Hemodialysis Catheter Exit Site Care, Arteriovenous Fistula and Graft Cannulation/Decannulation, Dialysis Station Routine Disinfection, and Injection Safety. 2) Increased number for facilities from 600 to 1,500 to accommodate the growing number of dialysis facilities anticipated over the next 3 years. These changes result in a net increase of 5,400 total burden hours for this form.

<b>Form No.</b>	<b>Name</b>	<b>Name in last ICR</b>	<b>Itemized Changes</b>	<b>Justifications</b>
<b>57.505</b>	Dialysis Patient Influenza Vaccination	No change	1) Replace ‘Flu vaccination date’ with ‘Event date.’ 2) Reword question “Was vaccine administered.” 3) Answer options for “Was vaccine administered” have been modified. 4) Increase number of annual respondents from 250 to 325.	1) Replacing “Flu Vaccination Date” with “Event Date” to be able to collect date information for patients vaccinated outside of the facility and for patients that declined vaccination. 2) This question was consolidated from three independent questions into one question for simplicity. 3) The answer options have been modified in order to guide the user through the paper form about what additional information will be required based on their selection. 4) Increased number of facilities from 250 to 325 to accommodate the growing number of dialysis facilities anticipated over the next 3 years. These changes result in an increase of 938 total burden hours.
<b>57.506</b>	Dialysis Patient Influenza Vaccination Denominator	No change	1) Increase number of annual respondents from 250 to 325.	1) Increased number of facilities from 250 to 325 to accommodate the growing number of dialysis facilities anticipated over the next 3 years. This change results in an increase of 63 total burden hours for this form.
<b>57.600</b>	State Health Department Validation Record	No change	No changes	N/A