

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	No changes	N/A
57.103	Patient Safety Component-Annual Facility Survey	No change	<ul style="list-style-type: none"> 1) Remove questions regarding Long Term Acute Care (LTAC) 2) Remove questions regarding Long Term Care Facilities (LTCF) 	Both of these sections were removed from this form because these questions are covered in newly added LTAC and LTCF Annual Surveys. These changes result in the decrease of 1000 burden hours.
57.104	Patient Safety Component-Outpatient Dialysis Center Practices Survey	No change	No changes	N/A
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	<ul style="list-style-type: none"> 1) Addition of section 'Underlying Conditions' that includes six check boxes. 2) Add field for Medicare ID number 	<p>1) The addition of these items and collection of data on the presence of these underlying conditions will be used to classify laboratory confirmed bloodstream infections due to translocation (TLCBI). This new LCBI classification will increase the specificity of the central line associated bloodstream infection (CLABSI) definition that is used for surveillance, quality measurement and public reporting. This modification to the definition is only for use in defined patient populations, those receiving chemotherapy treatments for cancer. Therefore, the additional burden (estimated to be 1 minute) to collect these items will not impact all NHSN facilities and locations, only those facilities and locations providing care to hematology-oncology and bone marrow transplant patients.</p> <p>2) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>These changes result in 3600 added burden hours.</p>
57.109	Dialysis Event	No change	<ul style="list-style-type: none"> 1) Addition of 'buttonhole' field under Risk Factors 2) Change 'Access Placement Date' from mm/dd/yyyy to 	<p>1) Buttonhole cannulation is a vascular access technique that will permit further risk-stratification of dialysis infection rates. Addition of this field has been requested by current users.</p> <p>2) Changing 'Access Placement Date' from</p>

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			<ul style="list-style-type: none"> mm/yyyy 3) Addition of 'transient patient' 4) Addition of 'None' problems 5) Add field for Medicare ID number 	<p>mm/dd/yyyy to mm/yyyy serves two purposes</p> <ul style="list-style-type: none"> a. Reduce data collection burden on users b. Allow users to report date information, even when day is unknown, instead of selecting 'unknown access placement date'. This change should improve data quality. <ul style="list-style-type: none"> 3) Current users have requested the ability to indicate when an event occurs in a 'transient patient'. 4) The dialysis event type 'pus, redness or increased swelling at the vascular access site' may occur without any other problems. Addition of a 'none' problems field will allow users to report no problems separately from the 'other problem, specify' field. 5) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. <p>These changes are only estimated add one minute to the time it takes for the form. Additionally, due to CMS mandated reporting, the number of respondents increased from 500 to 5,500. This combination adds 100,625 burden hours to the ICR.</p>
57.111	Pneumonia (PNEU)	No change	<ul style="list-style-type: none"> 1) Add field for Medicare ID number 	<ul style="list-style-type: none"> 1) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. <p>This change does not affect the estimated burden.</p>
57.112	Streamlined Ventilator-Associated Pneumonia (SVAP)	N/A. This is a new form.	<p>This is a new form specifically introduced to provide a streamlined, objective definition via which NHSN users may detect and report cases of ventilator-associated pneumonia in adult patients only. The burden on users will increase because initially we anticipate that users will conduct SVAP surveillance in conjunction with traditional NHSN PNEU surveillance. As experience with SVAP</p>	<p>The current NHSN PNEU definitions are regarded as complex and subjective. The new SVAP definition provides an alternative means of detecting and reporting ventilator-associated pneumonia events, and may eventually replace PNEU.</p> <p>This form adds an additional 360,000 burden hours to this ICR.</p>

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			surveillance increases, three options may be available to users: 1) they may choose to continue traditional NHSN PNEU surveillance alone; 2) they may continue to conduct SVAP surveillance in conjunction with traditional PNEU surveillance; or 3) they may opt to perform SVAP surveillance instead of traditional PNEU surveillance. It is possible that traditional NHSN PNEU surveillance may be phased out at some future date.	
57.114	Urinary Tract Infection (UTI)	No change	1) Add field for Medicare ID number	<p>1) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>This change does not affect the estimated burden.</p>
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	<p>1) Facilities will no longer have to collect denominator data for umbilical catheters separately from central lines.</p> <p>2) An optional field was created for counting the number of infants with a urinary catheter.</p>	<p>1) The rates of umbilical catheter-associated bloodstream infections (BSI) are not significantly different from the rates of central line-associated BSI to justify the stratification of central venous catheters into umbilical catheters and central lines. This modification will significantly reduce the burden in the data collection as personnel collecting the data will no longer have to determine the type of central venous catheter the infant has and to count the number of infants with an umbilical catheter separately from those with a central line.</p> <p>2) An optional field for urinary catheter has been created for facilities that want to monitor the number of infants with a urinary catheter. We anticipate a very small number of facilities collecting and reporting this data given that placement of an indwelling urinary catheter in infants is not a common practice and the voluntary nature of the reporting.</p> <p>These changes result in a decrease of 1 burden hour per response for a cumulative decrease of 54,000 burden hours.</p>
57.117	Denominators for Specialty Care Area (SCA)	No change	No changes	N/A
57.118	Denominators for	No change	No changes	N/A

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	Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)			
57.119	Denominator for Outpatient Dialysis	No change	<ol style="list-style-type: none"> 1) Addition of a sub-category to the current field 'Number fistula patients', 'Number of fistula patients who undergo buttonhole cannulation'. 	<p>1) Buttonhole cannulation is a vascular access technique that will permit further risk-stratification of dialysis infection rates. Addition of this field has been requested by current users.</p> <p>This change is only estimated to add one minute to the time it takes for the form. Additionally, due to CMS mandated reporting, the number of respondents increased from 500 to 5,500. This combination adds 6,100 burden hours to the ICR.</p>
57.120	Surgical Site Infection (SSI)	No change	<ol style="list-style-type: none"> 1) Expand "Detected" field, 'R' value into two response choices: 'RF – readmission to facility where procedure performed' and 'RO – readmission to facility other than where procedure was performed'. 2) Add field for Medicare ID number 	<p>1) The current definition of 'P – post-discharge surveillance' includes those infections detected upon admission to a facility other than where the procedure was performed. However, data validation efforts have revealed that some respondents have misclassified such infections as detected upon readmission ('R'). Therefore, we want to split the 'R' category into those detected upon readmission to the facility where the procedure was performed ('RF') and those detected in another facility ('RO'). Only those infections identified by other post-discharge detection methods would be included in the 'P' category. By understanding how/where the infection was detected, we can evaluate a facility's surveillance intensity and limit which infections are used to calculate comparative quality metrics.</p> <p>2) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>In addition to these changes, the estimated number of times a respondent would fill out this form is being increased from 27 to 36 times per year thus adding 28,800 burden hours.</p>
57.121	Denominator for Procedure	No change	<ol style="list-style-type: none"> 1) For all types of operative procedures, delete 'Non-autologous transplant' field 2) For CSEC operative procedures, delete 'Estimated blood loss' field. 3) Add field for Medicare 	<p>1) Because this form may be imported into the NHSN application in the Clinical Document Architecture (CDA) format from vendor systems, vendors need time to reprogram their applications. NHSN has agreed to allow vendors one year for such work. Therefore, the currently approved form will not be implemented into the NHSN application until 2013. In</p>

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			ID number	<p>the meantime, we propose to continue to use the previously approved version of the form, but to ease data collection burden, would like to delete two data fields that have not proved valuable in assessing surgical site infection risk based on our logistic regression model analyses. The deletion of these two fields was already incorporated into the changes on the currently approved form.</p> <p>2) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>This change decreases burden by 2 minutes per response for an overall decrease of 108,000 burden hours.</p>
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	<ol style="list-style-type: none"> 1) Expand response options to include Advanced Practice Nurse and Registered Nurse. 2) Remove PICC Team and IV Team response options from "Occupation of Inserter" question and make into separate question. 3) Add question to determine why chlorhexidine would not have been used for skin preparation. 4) Add question to determine if insertion attempt was successful. 5) Add field for Medicare ID number 	<ol style="list-style-type: none"> 1) The answer options for the question "Occupation of Inserter" were expanded to include Advanced Practice Nurse and Registered Nurse, as these were missing and needed. 2) The answer options PICC Team and IV Team were removed from the "Occupation of Inserter" question, as they were not appropriate answers for "Occupation" and were causing confusion. In order to continue to collect this important information, a Yes/No question was added, following the "Occupation of Inserter" question, to ask whether the inserter was a member of a PICC or IV Team. 3) The CDC/HICPAC guidelines for central-line insertion practices state that chlorhexidine should be used for skin preparation, unless there is a contraindication for the patient. So, in order to evaluate appropriate adherence to the insertion practices, a question was added, to be asked and answered only if chlorhexidine was not used for the preparation, to allow documentation of a contraindication, which would could

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				<p>then still be scored as appropriate compliance.</p> <p>4) We have learned from users that there may be situations where multiple attempts are made before a central line is successfully inserted. We do need to know about all attempts, but we also need to distinguish between failed attempts and successful insertions. Therefore, a Yes/No question was added to ask whether the specific attempt resulted in a successful central line placement.</p> <p>5) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>In addition to these changes, the number of estimated respondents was decreased from 6,000 to 1,000 due to the lack of mandated CLIP reporting. These changes result in a decrease in 41,667 burden hours.</p>
57.126	MDRO or CDI Infection Form	No change	<p>1) Added NEC criteria</p> <p>2) Add field for Medicare ID number</p>	<p>1) The definition of necrotizing enterocolitis (NEC) was recently updated and will be available for NSHN users starting January 2012. NEC is relevant to many enteric pathogens included in the MDRO/CDI module. Therefore, the updated NEC criteria was added to this form.</p> <p>2) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>These changes do not affect the estimated burden.</p>
57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	No change	No changes	N/A
57.128	Laboratory-identified MDRO or CDI Event	No change	<p>1) Add field for Medicare ID number</p> <p>2) Decrease burden from 30 minutes to 15 minutes per response.</p>	<p>1) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number.</p> <p>2) The burden per response for this form was decreased from 30 minutes to 15 minutes per feedback from the form users.</p> <p>These changes result in an overall burden decrease of 240,000 hours.</p>
57.130	Vaccination Monthly Monitoring Form-	High Risk Inpatient	<p>1) Title change to reflect instrument.</p>	<p>1) Title change to reflect instrument.</p> <p>This change does not affect the estimated</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
	Summary Method	Influenza Vaccination Monthly Monitoring Form- Method A		burden.
57.131	Vaccination Monthly Monitoring Form- Patient-Level Method	High Risk Inpatient Influenza Vaccination Monthly Monitoring Form- Method B	1) Title change to reflect instrument.	1) Title change to reflect instrument. This change does not affect the estimated burden.
57.133	Patient Vaccination	No change	1) Add field for Medicare ID number	1) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. This change does not affect the estimated burden.
57.137	Patient Safety Component-Annual Facility Survey for LTCF	No change	1) Add question for number of pediatric beds in facility 2) Add response choice of 'hospice/palliative'	1) There are a small number of LTCFs, skilled nursing facilities and nursing homes, which focus on pediatric patient populations. This field was added to enable NHSN to identify facilities with this specialized focus in pediatric LTC because the data reported from these facilities may be significantly different from the data reported from adult LTC facilities. 2) The response choice of 'hospice/palliative' was added at the users' request to help to further classify bed type within facilities. These changes do not affect the estimated burden.
57.138	Laboratory-identified MDRO or CDI Event for LTCF	No change	1) Add 'date of current admission to facility' 2) Add response choice of 'hospice/palliative' to Primary resident service type 3) Decrease burden from 30 minutes to 15 minutes per response.	1) For many individuals, a LTCF serves as their home. Lengths of stay in these facilities could be months to many years depending on the type of facility. However, with acute illnesses, a resident may transfer from the LTCF to a hospital for management of the new condition and then return back to the LTCF a few days later. A resident could have been residing in a LTCF for years before that recent hospital admission. Capturing these transitions in care and their relationship to the onset of new infection events may be important in understanding the epidemiology of LTCF-onset infections. Therefore, this field was added to the form to capture more recent transitions in care (date of

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				<p>current admission).</p> <p>2) This response choice of 'hospice/palliative' was added at the users' request to help remove confusion and further classify service type within facilities.</p> <p>3) The burden per response for this form was decreased from 30 minutes to 15 minutes per feedback from the form users.</p> <p>These changes result in an overall burden decrease of 500 hours.</p>
57.139	MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	No change	<ol style="list-style-type: none"> 1) Remove 'infection surveillance' reporting fields. 2) Remove 'blood specimen only LabID' reporting fields. 3) Remove process measures of hand hygiene and gown and glove use. 4) Decrease burden from 7 minutes to 5 minutes per response. 	<p>1) These reporting fields were removed because this type of reporting is no longer allowed within the module.</p> <p>2) These reporting fields were removed because this type of reporting is no longer allowed within the module.</p> <p>3) These process measures were removed from this form and made into a new form (Prevention Process Measures Monthly) to allow users to focus on one type of reporting at a time.</p> <p>4) The burden per response for this form was decreased from 7 minutes to 5 due to a typo on the previous form submission.</p> <p>These changes result decrease of 26 burden hours.</p>
57.140	Urinary Tract Infection (UTI) for LTCF	High Risk Inpatient Influenza Vaccination Denominator Data Form – Method B	<ol style="list-style-type: none"> 1) Add 'date of current admission to facility' 2) Add response option of 'unknown' to site where the device was inserted 3) Separate 'indwelling/suprapubic' into two response choices for device type 4) Add response option of 'symptomatic CA-UTI (CA-SUTI) to specific event 5) Title change to reflect instrument. 	<p>1) For many individuals, a LTCF serves as their home. Lengths of stay in these facilities could be months to many years depending on the type of facility. However, with acute illnesses, a resident may transfer from the LTCF to a hospital for management of the new condition and then return back to the LTCF a few days later. A resident could have been residing in a LTCF for years before that recent hospital admission. Capturing these transitions in care and their relationship to the onset of new infection events may be important in understanding the epidemiology of LTCF-onset infections. Therefore, this field was added to the form to capture more recent transitions in care (date of current admission).</p> <p>2) This response choice of 'unknown' was added to allow users to further classify where the device was inserted.</p> <p>3) Separating the response choice of 'indwelling/suprapubic' into two separate responses allows users to delineate between the two device types'</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				<p>data.</p> <p>4) Urinary tract infections (UTI) are the most commonly diagnosed infection in LTC settings and account for substantial antibiotic use in this population. Unlike the Patient Safety component which focuses on catheter-associated UTI events, the LTC component allows for reporting of all UTI events. This field was a minor addition to enable the user to differentiate catheter associated symptomatic UTI from those which were not catheter-related.</p> <p>5) Title change to reflect instrument. These changes result in no change of the estimated burden.</p>
57.141	Monthly Reporting Plan for LTCF	N/A. This is a new form.		
57.142	Denominators for LTCF Locations	N/A. This is a new form.		
57.143	Prevention Process Measures Monthly Monitoring for LTCF	N/A. This is a new form.	<p>These three forms, intended for use in long-term care facilities (LTCFs), are adaptations of previously-approved NHSN data collection forms specific to acute-care facilities. NHSN plans to expand its current HAI surveillance population to include LTCFs in the near future to support CMS and HHS HAI directives toward HAI surveillance in this setting. As the LTCF HAI data collection capabilities will be built within the existing NHSN web interface, we request approval of these forms as a revision the current NHSN ICR (0920-0666).</p>	<p>A new Long-Term Care Facility (LTCF) Component is under development within NHSN, in order to more specifically and appropriately capture data from the residents of skilled nursing facilities. This component was to be launched in 2011, but the release has now been postponed until 2012. With the first version of this new component, users will be able to track and report urinary tract infections (UTIs), laboratory-identified (LabID) events for multidrug-resistant organisms and <i>C. difficile</i>, and/or hand hygiene and gown and gloves use, all at the facility-wide inpatient level. In order to facilitate this reporting, there are 7 LTCF forms that have been created by using forms from the Patient Safety Component as a base, with modifications to specifically address the nuances of LTC residents. In the last OMB package submission from NHSN, 4 of the forms were included and approved. However, due to an unexpected oversight, 3 of the forms were not included in that package. Therefore, we are including those 3 remaining LTCF forms in this package submission for review and approval. The 3 LTCF forms that we are submitting in the current OMB package include:</p> <p>1) Monthly Reporting Plan, which is used to indicate the events to be monitored by the facility in the month. This information is required to guide the expectations of the system for the data that will be submitted in the coming month.</p> <p>2) Denominator form for UTI reporting, which is used to collect the necessary and required resident day and urinary catheter day counts for the facility each</p>

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				<p>month. This information is necessary to calculate rates, if UTIs are being monitored in that month.</p> <p>3) Hand Hygiene and Gown and Gloves Use Process Measures form to report appropriate performed/used (numerator) and indicated (denominator) aggregate counts in a month. This information is required if adherence to hand hygiene and/or gown and gloves use is chosen to be monitored in the month.</p> <p>Expanding NHSN surveillance to LTCFs with the use of these three forms will add approximately 9,500 burden hours to this ICR.</p>
57.150	Patient Safety Component- Annual Facility Survey for LTAC	N/A. This is a new form.	Addition of Long-Term Acute Care Facility Survey.	The CMS final rule for the FY 2012 IPPS includes a requirement for long-term acute care (LTAC) hospitals to report CAUTI and CLABSI data to NHSN by October 2012. As a result, all LTAC hospitals in the U.S. will be required to enroll in and report to NHSN. Since LTAC hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an LTAC-specific annual survey which will capture facility-level data specific and relevant to LTAC hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from LTAC hospitals. This form adds an additional 200 burden hours to the ICR.
57.151	Patient Safety Component-Annual Facility Survey for IRF	N/A. This is a new form.	The Annual Facility Survey for IRFs has adapted the Annual Facility survey to ask questions more applicable for Inpatient Rehabilitation Facilities (IRF) to better characterize IRF which are enrolling in NHSN.	The CMS final rule for the FY 2012 IPPS includes a requirement for inpatient rehabilitation facilities (IRF) hospitals to report CAUTI to NHSN by October 2012. As a result, all certified IRF hospitals in the U.S. will be required to enroll in and report to NHSN. Since IRF hospitals will be reporting as their own unique facility type, separate from acute care hospitals, there is a need for an IRF-specific annual survey which will capture facility-level data specific and relevant to IRF hospitals. The annual survey data are used for risk stratification and development of appropriate SIRs for reporting of data from IRF hospitals. This form adds an additional 417 burden hours to the ICR.
57.200	Healthcare Personnel Safety Component Annual Facility Survey	No change	No changes	N/A
57.202	Healthcare Worker Survey	No change	No changes	N/A
57.203	Healthcare Personnel	No change	No changes	N/A

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
	Safety Monthly Reporting Plan			
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	Healthcare Worker Post-exposure Prophylaxis	1) Title change to reflect instrument.	1) Title change to reflect instrument. This change does not affect the estimated burden.
57.207	Follow-Up Laboratory Testing	No change	No changes	N/A
57.208	Healthcare Worker Vaccination History	No change	No changes	N/A
57.209	Healthcare Worker Influenza Vaccination	No change	No changes	N/A
57.210	Healthcare Worker Prophylaxis/Treatment-Influenza	Healthcare Worker Influenza Antiviral Medication Administration	1) Title change to reflect instrument.	1) Title change to reflect instrument. This change does not affect the estimated burden.
57.211	Pre-season Survey on Influenza Vaccination Programs for Healthcare Personnel	No change	No changes	N/A
57.212	Post-season Survey on Influenza Vaccination Programs for Healthcare Personnel	No change	No changes	N/A
57.213	Healthcare Personnel Influenza Vaccination Monthly Summary	No change	No changes	N/A
57.300	Hemovigilance Module Annual Survey	No change	1) Add response option of 'TJC' (The Joint Commission) for accreditation 2) Change 'Emergency Room' to 'Emergency Department' in response choices throughout the form 3) Add new question about point-of-use bacterial testing on platelets prior to transfusion 4) Add response choices of 'BBCS®,' 'BloodTrack Tx® (Haemonetics)' to computerized transfusion services question 5) Change 'Wyndgate®,'	1) The Joint Commission is actively involved in accrediting transfusion medicine laboratories and should be included as an option on our survey. 2) To user proper terminology for the Emergency Department. 3) Bacterial contamination of platelets is a primary source of transfusion-transmitted infections, and rapid testing methods may be effective in preventing these transmissions. We would like to gauge the magnitude of point-of-issue bacterial contamination testing as the technology becomes available. 4) Software vendors must be periodically updated as they rapidly change within the industry. 5) Software vendors must be periodically updated as they rapidly change within the industry.

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
			to 'Safetrace Tx®' under computerized transfusion services question 6) Change 'are' to 'is' for question about routine type and screen	6) To use proper grammar. These changes do not affect the estimated burden.
57.301	Hemovigilance Module Monthly Reporting Plan	No change	No changes	N/A
57.302	Hemovigilance Module Monthly Incident Summary	Hemovigilance Module Blood Product Incident Reporting-Summary Data	1) Title change to reflect instrument.	1) Title change to reflect instrument. This change does not affect the estimated burden.
57.303	Hemovigilance Module Monthly Reporting Denominators	No change	No changes	N/A
57.304	Hemovigilance Adverse Reaction	No change	1) Changed order of sections on the form to Investigation Results, Outcome, and the Component Details 2) Changed option question 'Was a particular unit implicated in the adverse reaction?' to be required 3) Added a field for Medicare ID number 4) Corrected spelling of 'pruritus' 5) Corrected word 'transfusion' under the Infection adverse reaction 6) Added options for 'ISBT' and 'Codabar' labeling system to each row of the Component Details section 7) Change 'Facility location where reaction occurred' to 'Facility location where patient was transfused' 8) Add 'Unit collection date/time' data fields as optional elements in Component Details table	1) To accommodate new business rule for 'unitimplicated' questions. 2) To accommodate new business rule for 'unitimplicated' questions. 3) In order to assist CMS with appropriate patient and facility identification, they have requested the addition of a variable to collect the patient's Medicare Beneficiary number. 4) To correct misspelled word. 5) To correct cut and paste error in last round of changes. 6) To allow multisource unit entry in a single adverse reaction form. 7) In order to best target prevention efforts, we should know where the patient is being transfused rather their location when they eventually develop an adverse reaction as they could occur hours or even days post transfusion. 8) Age of a blood component is an important risk factor in transfusion-related adverse reactions. Currently we have no way to capture or calculate the age of a product at the time of transfusion. These changes do not affect the estimated burden.
57.305	Hemovigilance Incident	No change	1) Changed the order that	1) To allow multisource unit entry in a

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			<p>‘Product Destroyed’ details are collected and added options for ‘ISBT’ and ‘Codbar’ labeling system for each product entered</p> <p>2) Reward response options for Incident result question</p>	<p>single incident form.</p> <p>2) The standard language for Incident Result question is not well understood by the users. We are rephrasing the options without changing the meaning to aid the user in accurate coding of incidents.</p> <p>These changes do not affect the estimated burden.</p>