## **Itemized IC Revisions and Justifications**

## Form No. in Red \*\*: form changes

## Form No. in Green: Change in burden/response

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	1. The number of respondents increased from 5,000 to 5,175.  2. Modify question #30.  3. Modify Response option #51.	1. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden. Annual facility participation in the Patient Safety Component increased during the 2019 reporting year due to growth in the number of facilities participating in NHSN.  2. Question modified to identify if administering antimicrobials to well-baby newborns was a routine practice in a facility.  3. Additional options added after reviewing free-text responses from previous survey.  These changes will increase the annual burden of this form
**57.104	NHSN Facility Administrator Change Request Form	No change	The number of respondents increased from 0 to 800.	by 219 hours.  1. This is a new form that will be completed by facility administrators when changes are made to the users at the facility who may no longer have access to NHSN or no longer employed by the facility. This form will be completed to inform changes that NHSN staff will make within the application. This form is intended to be made electronic by NHSN shortly after it is rolled out.  These changes will increase the annual burden of this form by 67 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	<ol> <li>Response options for event-related "Risk Factors" were updated from optional to required.</li> <li>The number of respondents decreased from 6,000 to 5,775.</li> <li>The number of responses per respondent decreased</li> </ol>	Response options were changed from optional to required after being optional for the first time being introduced to NHSN.      Annual facility participation decreased during the 2019 reporting year. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports

Form No.	Name	Name in last ICR	Item	ized Changes	Justii	ications
				from 44 to 5.		were used to assist with estimating annual burden and
			4.	Annual time burden for		identified that, in 2018, 5,500 facilities submitted at
				the form increased from		least 1 Device-associated Summary Form. We added
				33 to 38 minutes.		5% (275) to 5500 to represent an estimate of events
			5.	Update response options		that will need to be reported that were not previously
				in the pathogens and		reported due to a data field moving from optional to
				susceptibility section		required.
				with a name change of	3.	Responses were updated based on the number of
				the organism 'Klebsiella'		events reported by respondents to NHSN.
				from 'Enterobacter'.	4.	Time burden increased to account for the responses to
						the form being required instead of optional for
					_	complete reporting into NHSN.
					5.	This change to the pathogens and susceptibility
						section is due to a name change for the organism from
						Enterobacter to Klebsiella. The name change is going
						into effect in January 2020.
					Thes	e changes will decrease the annual burden of this form
						26,913 hours.
**57.111	Pneumonia (PNEU)	No change	1.	The number of responses	1.	The number of times this form is completed annually
				per respondent decreased		by participants was updated to reflect an accurate
				from 72 to 30.		number of annual responses to this form for complete
			2.	Update response options		reporting into NHSN and the overall reduction of
				in the pathogens and		burden. NHSN created new reports in 2019 that
				susceptibility section		accurately provide the number of facilities that have
				with a name change of		reported to NHSN during the previous calendar year
				the organism 'Klebsiella'		and indicate the number of times an event form is
				from 'Enterobacter'.		entered into NHSN (number of responses) for data
						reporting purposes. These reports were used to assist
						with estimating annual burden and identified that we
						over-estimated the number of responses per
					2.	respondent in 2018.
					۷٠	This change to the pathogens and susceptibility
						section is due to a name change for the organism from
						Enterobacter to Klebsiella. The name change is going
					Thos	into effect in January 2020.
						e changes will decrease the annual burden of this form 7,800 hours.
**57.112	Ventilator-Associated Event	No change	1.	The number of	1.	Annual facility participation decreased during the 2019
		_		respondents decreased		reporting year. As of 10/1/2018 (after reporting
				from 5,615 to 5,463.		deadline of 2/18/2019), CMS no longer requires
			2.	The number of responses		reporting of Ventilator-Associated Event (VAE) by
				per respondent decreased		long-term acute care hospitals (LTACs), so we
				from 144 to 5.		anticipate that some LTACs will no longer report these
			3.	Update response options		events and associated summary data to NHSN.
				in the pathogens and		Therefore, an estimate of 25% of LTACs will be
				susceptibility section		removed from the numbers. 609 LTACs are enrolled

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
**57.113	Pediatric Ventilator- Associated Event (PedVAE)	Name in last ICR  No change	1. The number of respondents increased from 100 to 334. 2. Update response options in the pathogens and susceptibility section with a name change of the organism 'Klebsiella' from 'Enterobacter'.	in NHSN currently. 25% of 609 is 152, which were removed from the numbers.  2. Responses were updated based on the number of events reported by respondents to NHSN in 2018. A total of 25,500 VAEs were reported, which rounds to approx. 5 events per facility.  3. This change to the pathogens and susceptibility section is due to a name change for the organism from Enterobacter to Klebsiella. The name change is going into effect in January 2020.  These changes will decrease the annual burden of this form by 364,495 hours.  1. Annual facility participation increased during the 2019 reporting year based on our revised estimation. There are 240 hospitals in PA according to Google, and 220 children's hospital in the US. All PA hospitals are required by their state to report, and we can estimate that 25% of children's hospitals will voluntarily report (55). We can estimate that 10% of the 3900 US hospitals enrolled in general hospitals enrolled in NHSN will report (recognizing a few of these will be duplicates from PA hospitals) (39). 240+55+39=334.  2. This change to the pathogens and susceptibility section is due to a name change for the organism from Enterobacter to Klebsiella. The name change is going into effect in January 2020.
**57.114	Urinary Tract Infection (UTI)	No change	<ol> <li>The number of respondents decreased from 6,000 to 5,500</li> <li>The number of responses per respondent decreased from 40 to 5.</li> <li>Update response options in the pathogens and susceptibility section with a name change of the organism 'Klebsiella' from 'Enterobacter'.</li> </ol>	These changes will increase the annual burden of this form by 14,040 hours.  1. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden and identified that 5,500 facilities submitted at least 1 Device-associated Summary Form in 2018.  2. Responses were updated based on the number of events reported by respondents to NHSN. Through our new reports, we identified that 25,700 catheter-associated UTIs were reported by 5,500 facilities for average of 5 events (responses)/facility.  3. This change to the pathogens and susceptibility section is due to a name change for the organism from

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				Enterobacter to Klebsiella. The name change is going into effect in January 2020.  These changes will decrease the annual burden of this form
**57.115	Custom Event	No Change	Update response options     in the pathogens and     susceptibility section     with a name change of     the organism 'Klebsiella'	<ol> <li>This change to the pathogens and susceptibility section is due to a name change for the organism from Enterobacter to Klebsiella. The name change is going into effect in January 2020.</li> </ol>
57.116	Denominators for Neonatal Intensive Care Unit (NICU)	No change	from 'Enterobacter'.  1. The number of respondents decreased from 6,000 to 220.  2. Time burden for this form increased by from 4 hours to 4.15 hours or (240 to 249 minutes).	<ol> <li>NHSN has revised the methods used to calculate the annual burden for this form. The number of device-associated summary forms were determined by the number of each form completed of each type divided by the number of facilities completing each type of denominator form.</li> <li>Time burden increased to account for the amount of time it takes for accurate and complete reporting into NHSN. The 15-minute increase is due to the addition of optional reporting for patient days and ventilator days by Gestational Age Categories.</li> <li>3.</li> </ol>
				These changes will decrease the annual burden of this form by 205,044 hours.
57.117	Denominators for Specialty Care Area (SCA)/Oncology (ONC)	No change	<ol> <li>The number of respondents decreased from 2,000 to 500.</li> <li>The number of responses per respondent increased from 9 to 21.</li> </ol>	1. NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden. The number of device-associated Summary Forms were determined by the number of each form completed of each type divided by the number of facilities completing each type of denominator form. NHSN has decreased the anticipated respondents accordingly, to account for accurate reporting of this form.  2. The number of responses was increased to account for increased annual reporting on this form into NHSN based on data collected from NHSN's internal reports.

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				These changes will decrease the annual burden of this form
				by 60,634 hours.
57.118	Denominators for Intensive Care Unit (ICU)/Other Locations (Not NICU or SCA)	No change	1. The number of respondents decreased from 6,000 to 5,500	1. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden and identified that annual facility completion of this form is estimated to decrease during the 2019 reporting year. The number of device-associated Summary Forms were
			1	determined by the number of each form completed of each type divided by the number of facilities completing each type of denominator form.  This change will decrease the annual burden of this form by 151,000 hours.
**57.120	Surgical Site Infection (SSI)	No change	<ol> <li>The number of respondents decreased from 6,000 to 4,500</li> <li>The number of responses per respondent decreased from 36 to 11.</li> <li>Update response options in the pathogens and susceptibility section with a name change of the organism 'Klebsiella' from 'Enterobacter'.</li> </ol>	<ol> <li>NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden. NHSN has decreased the anticipated respondents accordingly, to account for accurate reporting of this form.</li> <li>The number of responses was decreased to account for decreased annual reporting on this form into NHSN.</li> <li>This change to the pathogens and susceptibility section is due to a name change for the organism from Enterobacter to Klebsiella. The name change is going into effect in January 2020.</li> <li>These changes will decrease the annual burden of this form</li> </ol>
57.121	Denominator for Procedure	No change	<ol> <li>The number of respondents decreased from 6,000 to 4,500</li> <li>The number of responses per respondent increased from 540 to 680</li> </ol>	1. NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden. NHSN has decreased the anticipated respondents accordingly, to account for accurate reporting of this

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.122	HAI Progress Report State	N/A		form.  2. The number of responses was increased to account for increased annual reporting on this form into NHSN.  These changes will decrease the annual burden of this form by 30,000 hours.
57.123	Health Department Survey  Antimicrobial Use and Resistance (AUR)- Microbiology Data Electronic Upload Specification Tables	No change	1. Increase the number of annual respondents from 1,000 to 1,500.	Annual facility participation increased during the     2019 reporting year due to outreach and education     efforts conducted by CDC, health departments, and     various HAI partners to encourage facilities to report     AUR data in NHSN.  This change will increase the annual burden of this form by     500 hours.
57.124	Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	No change	No change	N/A
57.125	Central Line Insertion Practices (CLIP) Adherence Monitoring	No change	Increase the number of reporting facilities from 100 to 500.     Increase the number of annual responses from 100 to 213.	<ol> <li>NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden and identified that, in 2018, 500 facilities reported an event using this form. This number is expected to be the same for 2019.</li> <li>The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN. We divided the total number of CLIP events reported (106,700) by 500 facilities reporting them to get 213 responses per facility.</li> <li>These changes will increase the annual burden of this form by 40,208 hours.</li> </ol>
**57.126	MDRO or CDI Infection Form	No change	Decrease the number of annual respondents from 6,000 to 720.     Decrease the number of annual responses from 72 to 12.     Update response options	NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports

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**57.127	MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	No change	in the pathogens and susceptibility section with a name change of the organism 'Klebsiella' from 'Enterobacter'.  1. Add MSSA Column to form. 2. Increase the number of respondents from 4,930 to 5,550. 3. The number of responses per respondent increased from 24 to 29.	were used to assist with estimating annual burden and identified that, in 2018, there were 8,364 non-LabID MDRO infection events reported from 719 facilities, for an average of 11.6 events per facility-year.  Estimates for 2019 were rounded up to 720 facilities, 12 per facility per year. NHSN has decreased the anticipated respondents accordingly, to account for accurate reporting of this form.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN.  3. This change to the pathogens and susceptibility section is due to a name change for the organism from Enterobacter to Klebsiella. The name change is going into effect in January 2020.  These changes will decrease the annual burden of this form by 211,680 hours.  1. The revision will make the section more concise and easier to identify by reporting facilities and NHSN users. Currently, each MDRO/CDI organism is listed with a separate column, except MSSA. Adding MSSA as a separate column will improve the accuracy of HAI reporting and allow for MSSA-specific data analysis.  2. Annual facility participation increased during the 2019 reporting year. 5,500 facilities reported at least 1 MDRO/CDI Summary form in 2018.  3. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN. 161,200 forms were submitted by a total of 5,500 facilities; 161,200 / 5500 = 29.
57.128	Laboratory-identified MDRO or CDI Event	No change	<ol> <li>Decrease number of respondents from 4,930 to 4,800.</li> <li>Decrease the number of annual responses from 240 to 87.</li> </ol>	1. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden to determine that facility respondents will decrease during the 2019 reporting year. Beginning October 1, 2018 (after reporting deadline of Feb. 18, 2019), CMS discontinued requirements for facilities participating in the Long-

Form No. Name	Name in last ICR	Itemized Changes	Justifications
			term Acute Care Hospital quality reporting program and the Inpatient Rehabilitation Facility quality reporting program to report NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716). Thus, the number of respondents for this form decreased resulting from these changes by CMS.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN.  These changes will decrease the annual burden of this form
57.129 Adult Sepsis	No change	No change	by 255,200 hours.  N/A
57.129 Adult Sepsis  Long-Term Care Facility Component – Respiratory Tract Infection  57.137 Long-Term Care (LTC) Facility Component – Annual Facility Survey	No change  No change	1. New Optional Form  1. Decrease number of respondents from 2,600 to 2,220.	1. For 2020, prior to introducing the new module and form to NHSN users, the CDC's Epidemiology Research & Innovations (ERIB) team will use the form to perform field testing of the form variables to explore the utilization, applicability, and data collection burden associated with these variables. This process will inform areas of improvement prior to incorporating the new module, including protocol, forms, and instructions into NHSN.  These changes will increase the annual burden of this form by 2,400 hours.  1. NHSN has revised the methods used to calculate the annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of
			times an event form is entered into NHSN (number of responses) for data reporting purposes. These reports were used to assist with estimating annual burden and identified an overestimation in 2018. Thus, annual LTC facility response for this form is estimated to decrease during the 2019 reporting year.  This change will decrease the annual burden of this form by 760 hours
**57.138 Laboratory-identified MDRO or CDI Event for LTCF	No change	Remove response option for "Social Security Number"     Remove response option for "Resident Type."     Decrease the time burden	<ol> <li>The resident social security number is being removed from all event forms since the information is not required to identify residents.</li> <li>The resident type will be auto-populated by the NHSN application.</li> <li>Time burden for this form will be decreased by 5</li> </ol>
			2. Remove response option for "Resident Type."

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				minutes.	4.	Annual facility participation decreased during the
			4.	Decrease number of		2019 reporting year.
				respondents from 2,600	5.	The number of times this form is completed annually
				to 2,150.		by participants was updated to reflect an accurate
			5.	Increase the number of		number of annual responses to this form for complete
				responses per respondent		reporting into NHSN.
				from 12 to 24.		
					These	e changes will increase the annual burden of this form
					by 5,	100 hours.
57.139	MDRO and CDI LabID Event	No change	1.	Decrease number of	2.	NHSN has revised the methods used to calculate the
	Reporting			respondents from 2,600		annual burden for this form. NHSN created new
	Monthly Summary Data for			to 2,220.		reports in 2019 that accurately provide the number of
	LTCF					facilities that have reported to NHSN during the
						previous calendar year and indicate the number of
						times an event form is entered into NHSN (number of
						responses) for data reporting purposes. These reports
						were used to assist with estimating annual burden and
						identified an overestimation in 2018. Thus, annual
						LTC facility response for this form is estimated to
						decrease during the 2019 reporting year.
					This	change will decrease the annual burden of this form by
						hours.
**57.140	Urinary Tract Infection (UTI)	No change	1.	Decrease number of	6.	NHSN has revised the methods used to calculate the
	for LTCF			respondents from 2,600		annual burden for this form. NHSN created new
				to 400.		reports in 2019 that accurately provide the number of
			2.	Remove response option		facilities that have reported to NHSN during the
				for "Social Security		previous calendar year and indicate the number of
				Number."		times an event form is entered into NHSN (number of
			3.	Remove response option		responses) for data reporting purposes. These reports
				for "Resident Type."		were used to assist with estimating annual burden and
			4.	Modify answer choices		identified an overestimation in 2018. Thus, annual
				to remove specimen		LTC facility response for this form is estimated to
				collection type.		decrease during the 2019 reporting year.
			5.	Decrease the time burden	7.	The resident social security number is being removed
				from 35 minutes to 30		from all event forms since the information is not
				minutes per response.		required to identify residents.
			6.	Update response options	8.	The resident type will be auto-populated by the
				with the newly classified		NHSN application.
				'Klebsiella' organism, in	9.	Specimen collection method removed from the form
				the pathogens and		and only one urine culture laboratory selection
				susceptibility section.		available since UTI criteria are the same for all
				'Klebsiella' from		specimen collection methods.
				'Enterobacter'.	10.	Time burden for this form will be decreased by 5
						minutes.
					11.	Add the 'Klebsiella' organism the pathogens and
						susceptibility section. This change to the pathogens

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				and susceptibility section is due to a name change for
				the organism from Enterobacter to Klebsiella. The
				name change is going into effect in January 2020.
				These changes will decrease the annual burden of this form
				by 125,800 hours.
57.141	Monthly Reporting Plan for	No change	1. Decrease number of	2. NHSN has revised the methods used to calculate the
	LTCF		respondents from 2,600	annual burden for this form. NHSN created new
			to 2,220.	reports in 2019 that accurately provide the number of
				facilities that have reported to NHSN during the
				previous calendar year and indicate the number of
				times an event form is entered into NHSN (number of
				responses) for data reporting purposes. These reports
				were used to assist with estimating annual burden and
				identified an overestimation in 2018. Thus, annual
				LTC facility response for this form is estimated to
				decrease during the 2019 reporting year.
				This change will decrease the annual burden of this form by
F7 140	Donominator for LTCF	No alessa	1. Decrease number of	2. NHSN has revised the methods used to calculate the
57.142	Denominators for LTCF	No change		
	Locations		respondents from 2,600 to 2,220.	annual burden for this form. NHSN created new reports in 2019 that accurately provide the number of
			10 2,220.	facilities that have reported to NHSN during the
				previous calendar year and indicate the number of
				times an event form is entered into NHSN (number of
				responses) for data reporting purposes. These reports
				were used to assist with estimating annual burden and
				identified an overestimation in 2018. Thus, annual
				LTC facility response for this form is estimated to
				decrease during the 2019 reporting year.
				This change will decrease the annual burden of this form by
				19,000 hours.
57.143	Prevention Process Measures	No change	1. Decrease number of	1.NHSN has revised the methods used to calculate the
	Monthly Monitoring for		respondents from 2,600	annual burden for this form. NHSN created new reports in
	LTCF		to 375	2019 that accurately provide the number of facilities that
				have reported to NHSN during the previous calendar year
				and indicate the number of times an event form is entered
				into NHSN (number of responses) for data reporting
				purposes. These reports were used to assist with estimating
				annual burden and identified an overestimation in 2018.
				Thus, annual LTC facility response for this form is
				estimated to decrease during the 2019 reporting year.
				2.
				This change will decrease the annual burden of this form by

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
				2,225 hours.
**57.150	Patient Safety Component-	No change	1. Modify response option	1. Additional options added after reviewing free-text
	Annual Facility Survey for		#42.	responses from previous survey.
	LTAC			This will not have an impact on the annual burden of this
				from.
**57.151	Patient Safety Component-	No change	1. Modify response option	1. Additional options added after reviewing free-text
	Annual Facility Survey for		#42.	responses from previous survey.
	IRF			This will not have an impact on the annual burden of this
				from.
57.200	Healthcare Personnel Safety	No change	No change	N/A
	Component Annual Facility			
	Survey			
57.203	Healthcare Personnel Safety	No change	No change	N/A
	Monthly Reporting Plan			
57.204	Healthcare Worker	No change	No change	N/A
	Demographic Data			
57.205	Exposure to Blood/Body	No change	No change	N/A
	Fluids			
57.206	Healthcare Worker	No change	No change	N/A
	Prophylaxis/Treatment			
57.207	Follow-Up Laboratory	No change	No change	N/A
37.207	Testing	Tro change	The change	
57.210	Healthcare Worker	No change	No change	N/A
57.210	Prophylaxis/Treatment-	110 Change	Two change	
	Influenza			
57.300	Hemovigilance Module	No change	No change	N/A
57.1500	Annual Survey	Tro change	The change	1921
57.301	Hemovigilance Module	No change	No change	N/A
	Monthly Reporting Plan		1.0	
57.303	Hemovigilance Module	No change	No change	N/A
37.1303	Monthly Reporting	Tro change	The change	
	Denominators			
57.304	Hemovigilance Adverse	No change	No change	N/A
37.304	Reaction	140 Change	140 Change	14/1
F7 20F		No shanga	No shange	N/A
57.305	Hemovigilance Incident	No change	No change	N/A
57.306	Hemovigilance Module	No change	No change	N/A
	Annual Survey - Non-Acute			
F7 207	Care Facility	No shang-	No shanga	N/A
57.307	Hemovigilance Adverse	No change	No change	N/A
	Reaction - Acute Hemolytic			
EE 200	Transfusion Reaction	N. I.	_	N/A
57.308	Hemovigilance Adverse	No change		N/A
	Reaction - Allergic			
	Transfusion Reaction			
57.309	Hemovigilance Adverse	No change		N/A
	Reaction - Delayed Hemolytic			
	Transfusion Reaction			

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57.310	Hemovigilance Adverse	No change		N/A
	Reaction - Delayed Serologic			
	Transfusion Reaction			
57.311	Hemovigilance Adverse	No change		N/A
	Reaction - Febrile Non-			
	hemolytic Transfusion  Reaction			
57.312	Hemovigilance Adverse	No change		N/A
37.312	Reaction - Hypotensive	140 Change		1471
	Transfusion Reaction			
57.313	Hemovigilance Adverse	No change		N/A
	Reaction - Infection			
57.314	Hemovigilance Adverse	No change		N/A
	Reaction - Post Transfusion			
	Purpura			
57.315	Hemovigilance Adverse	No change		N/A
	Reaction - Transfusion			
57.316	Associated Dyspnea Hemovigilance Adverse	No change		N/A
37.310	Reaction - Transfusion	140 Change		1471
	Associated Graft vs. Host			
	Disease			
57.317	Hemovigilance Adverse	No change		N/A
	Reaction - Transfusion			
	Related Acute Lung Injury			
57.318	Hemovigilance Adverse	No change		N/A
	Reaction - Transfusion			
	Associated Circulatory Overload			
57.319	Hemovigilance Adverse	No change		N/A
	Reaction - Unknown			
	Transfusion Reaction			
57.320	Hemovigilance Adverse	No change		N/A
	Reaction - Other Transfusion			
	Reaction		1	1
57.400	Outpatient Procedure	No change	1. Decrease the number of	1. NHSN has revised the reports used to calculate the
	Component (OPC)—Annual		annual respondents from	annual burden for this form. Reporting to OPC began
	Facility Survey		5,000 to 700.	in November 2018, and we overestimated the number of facilities actively reporting data to NHSN during
				the rollout of OPC. Previously reported facility
				information was based on the total number of ASC
				facilities using NHSN. We estimate 700 facilities
				reporting in 2019 based on 625 actual enrolled
				facilities using OPC and added 75 (12%) to allow for
				growth.
				This change will decrease the estimated annual burden of

Form No.	Name	Name in last ICR	Itemized Changes		fustifications	
					his form by 717 hour	S.
57.401	Outpatient Procedure Component - Monthly Reporting Plan (MRP)	No change	2.	Decrease the number of annual respondents from 5,000 to 700.  Decrease the time burden of this form by 5 minutes	annual burden f in November 20 of facilities acti the rollout of O information wa facilities using reporting in 201 facilities using growth. We ass facilities that co will complete a	sed the reports used to calculate the for this form. Reporting to OPC began D18, and we overestimated the number vely reporting data to NHSN during PC. Previously reported facility is based on the total number of ASC NHSN. We estimate 700 facilities 19 based on 625 actual enrolled OPC and added 75 (12%) to allow for sumed that the same number of ompleted the Annual Facility Survey MRP each month.  Inplete this form was decreased from 5 minutes.
					These changes will de	crease the estimated annual burden of ours.
57.402	Outpatient Procedure Component Same Day Outcome Measures (SDOM)	No change	1.	Decrease the number of annual respondents from 1,200 to 200.  Decreases the number of responses per respondent from 25 to 10.	annual burden fin November 20 of facilities acti the rollout of O information wa facilities using percentage (approximate) completed the fin SDOM and the events reported the participants number of annureporting into Nov. 2018, 354-2/quarter) events were 300 encounters per module 25%, this would give this was rounded up to the source of	sed the reports used to calculate the for this form. Reporting to OPC began D18, and we overestimated the number evely reporting data to NHSN during PC. Previously reported facility is based on the total number of ASC NHSN. We assumed that a small box. 25-28%) of the facilities that Annual Facility Survey will participate there will be a very low number of thus an estimate of 200 facilities. It is the things that is form is completed annually was updated to reflect an accurate that responses to this form for complete the encounters and 2-SDOM (approx. a reported. If we estimate an average of both, per facility, and an SDOM rate of the us a SDOM count of 9 per facility. The crease the estimated annual burden of the crease the cre
57.403	Outpatient Procedure  Component - Monthly  Denominators for Same Day	No change	1.	Decrease the number of annual respondents from 1,200 to 200.	1. NHSN has revi-	sed the reports used to calculate the for this form. Reporting to OPC began 018, and we overestimated the number
	Outcome Measures		2.	Increase the number of responses per respondent from 12 to 400.	of facilities acti	vely reporting data to NHSN during PC. Previously reported facility s based on the total number of ASC

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
57.404	Outpatient Procedure Component – SSI Denominators	No change	1. Decrease the number of annual respondents from 5,000 to 700.  2. Decrease the number of responses per respondent from 540 to 100.	facilities using NHSN. We assumed that a small percentage (approx. 25%) of the facilities that completed the Annual Facility Survey will participate in SDOM. The SDOM denominator is encounters. Since Nov 2018, the sum of encounters from 12 facility- months reporting is 3544.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN.  These changes will increase the estimated annual burden of this form by 43,733 hours.  1. NHSN has revised the reports used to calculate the annual burden for this form. Reporting to OPC began in November 2018, and we overestimated the number of facilities actively reporting data to NHSN during the rollout of OPC. Previously reported facility information was based on the total number of ASC facilities using NHSN. We estimate 700 facilities reporting in 2019 based on 625 actual enrolled facilities using OPC and added 75 (12%) to allow for growth. We assumed that all of the facilities that completed the Annual Facility Survey will more than likely participate in SSI surveillance.  2. We estimated 100 SSI Denominator records per facility/year with 5 SSI event records, based on 24,300 2018-SSI Denominator records for 642 OrgIDs = 40/year and 8 SSI events/year.
57.405	Outpatient Procedure Component - Surgical Site (SSI) Event	No change	Decrease the number of annual respondents from 5,000 to 700.     Decreases the number of responses per respondent from 36 to 5.	These changes will decrease the estimated annual burden of this form by 403,333 hours.  1. NHSN has revised the reports used to calculate the annual burden for this form. Reporting to OPC began in November 2018, and we overestimated the number of facilities actively reporting data to NHSN during the rollout of OPC. Previously reported facility information was based on the total number of ASC facilities using NHSN. We estimate 700 facilities reporting in 2019 based on 625 actual enrolled facilities using OPC and added 75 (12%) to allow for growth. We assumed that all of the facilities that completed the Annual Facility Survey will more than likely participate in SSI surveillance.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses based on the new

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
**57.500	Outpatient Dialysis Center	No change	Increase the number of	responses by facility reports we have implemented.  We estimated 5 SSI events per facility.  These changes will decrease the estimated annual burden of this form by 102,667 hours.
	Practices Survey		annual respondents from 7,000 to 7,100.  2. Response options modified for questions #3a, #20, and #64.  3. New required question added #9, #12, #65b.	<ul> <li>2019 reporting year due to newly enrolled dialysis facilities in NHSN.</li> <li>2. #3a) currently there are two major accrediting organizations. This modification will help eliminate false responses and therefore the data captured would reflect accurate information. #20) this addition is added because adverse events occur in the patient setting and will help inform guidelines for patient safety and reduction of bloodstream infections. #64) making each response option yes/no to make it easier for the users to respond to each option.</li> <li>3. #9) question added to estimate the prevalence of dialysis services in an outpatient setting provided by long term care facilities. #12) to accurately assess the infection control practices, which can inform best practices for reducing bloodstream infections.#65b) the addition of this question will inform future education/guidance for NHSN our users on best practices for catheter care and reduction of bloodstream infections.</li> <li>These changes will increase the estimated annual burden of this form by 212 hours.</li> </ul>
57.501	Dialysis Monthly Reporting Plan	No change	Increase the number of annual respondents from 7,000 to 7,100.     Decrease the burden per response per respondent from 20 to 15 minutes.	1. Annual facility participation increased during the 2019 reporting year due to newly enrolled dialysis facilities in NHSN.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN and the overall reduction of burden.  These changes will decrease the estimated annual burden of this form by 17,900 hours.
**57.502	Dialysis Event	No change	1. Increase the number of annual respondents from 7,000 to 7,100.	Annual facility participation increased during the     2019 reporting year due to newly enrolled dialysis     facilities in NHSN.

Form No.	Name	Name in last ICR	Item	ized Changes	Justifications
57.503	Denominators for Dialysis Event Surveillance	No change	<ol> <li>3.</li> <li>1.</li> </ol>	Decrease the number of responses per year from 60 to 30 responses annually.  Update response options in the pathogens and susceptibility section with a name change of the organism 'Klebsiella' from 'Enterobacter'.  Increase the number of annual respondents from 7,000 to 7,100.	2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN and the overall reduction of burden.  3. Updates will align the form with the NHSN application update for 2020.  These changes will decrease the estimated annual burden of this form by 86,250 hours.  1. Annual facility participation increased during the 2019 reporting year due to newly enrolled dialysis facilities in NHSN.  This change will increase the estimated annual burden of this form by 200 hours.
57.504	Prevention Process Measures  Monthly Monitoring for  Dialysis	No change	2.	Decrease the number of annual respondents from 2,000 to 1,760.  Decrease the time burden by 10 minutes from 85 to 75 minutes.	1. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN for data reporting purposes. These reports were used to assist with estimating annual burden and identified that annual facility response for this form would decrease during the 2019 reporting year.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN and the overall reduction of burden.  This change will decrease the estimated annual burden of this form by 7,600 hours.
57.505	Dialysis Patient Influenza Vaccination	No change	1.	Increase the number of annual respondents from 325 to 860.	3. NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN for data reporting purposes. These reports were used to assist with estimating annual burden and identified that annual facility response for this form would increase during the 2019 reporting year.
			1.		This change will increase the estimated annual burden of this form by 4,538 hours.  1. NHSN created new reports in 2019 that accurately

Form No.	Name	Name in last ICR	Itemized Changes	Justifications
			325 to 860.  2. Decrease the number of responses per year from 5 to 1 response annually.	NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN for data reporting purposes. These reports were used to assist with estimating annual burden and identified that annual facility response for this form would increase during the 2019 reporting year.  2. The number of times this form is completed annually by participants was updated to reflect an accurate number of annual responses to this form for complete reporting into NHSN and the overall reduction of burden.  These changes will decrease the estimated annual burden of this form by 199 hours.
**57.507	Home Dialysis Center Practices Survey	No change	<ol> <li>Increase the number of annual respondents from 325 to 430.</li> <li>Response options modified for questions #9, #19, #21, #27, #31, #33 and #37.</li> <li>New required question added #3, #7, #10, #11, #16, #20, and 38.</li> </ol>	<ol> <li>NHSN created new reports in 2019 that accurately provide the number of facilities that have reported to NHSN during the previous calendar year and indicate the number of times an event form is entered into NHSN for data reporting purposes. These reports were used to assist with estimating annual burden and identified that annual facility response for this form would increase during the 2019 reporting year.</li> <li>#9) this addition is added because adverse events occur in the patient setting and will help inform guidelines for patient safety and reduction of bloodstream infections. #19) and #21) reflects the accuracy of the patient setting. Patients in home hemodialysis care are not admitted to a center these patients receive care in a home setting.#27), #31) #33) changing "chlorhexidine with alcohol (e.g., Chloraprep®, Chlorasrub™)" to "chlorhexidine with alcohol (e.g., Chloraprep™, PDI Prevantics®)" to be more inclusive of products that meet or exceed the chlorhexidine recommendation.#37) making each response option 'yes/no' to make it easier for the users to respond to each question.</li> <li>#3) question added to have an accurate count of facilities who are accredited by an organization outside of CMS. #7) question added to estimate the prevalence of dialysis services in an outpatient setting provided by long term care facilities. #10) added to estimate how often bloodstream infections are due to hospital admissions. #11) to determine the ability a facility can obtain microbiology lab records from a hospital/dialysis facility communication. #16) added</li> </ol>

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				to understand and capture vaccination practices in
				home dialysis settings. Also, to estimate the number
				of each vaccination type (e.g., Hep B, influenza, and
				pneumococcal) received for home patients. #20)
				added to understand facilities screening practices for
				hepatitis C which will be used to inform future
				guidance and education for Hepatitis C in home
				hemodialysis settings. #38) added to understand
				facilities catheter care practices and policies. This
				addition will inform future education/guidance to our
				users on best practices for catheter care and reduction
				of bloodstream infections.
				These changes will increase the estimated annual burden of
				this form by 40 hours.