National Healthcare Safety Network (NHSN)
OMB Control No. 0920-0666
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Revision Request
Supporting Statement Part A

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- Since 2005, the National Healthcare Safety Network (NHSN) provides facilities, states, regions, and the nation with the data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs). Participation in NHSN has continuously increased since 2005, with over 22,000 reporting facilities to date. Reducing and preventing HAIs and increasing patient safety and the value of federally funded healthcare coverage are top priorities for the Department of Health and Human Services (DHHS). In pursuit of these Departmental goals, CDC works closely with the Centers for Medicare and Medicaid Services (CMS) to enable use of NHSN data in CDC's surveillance and prevention programs and CMS's quality improvement, public reporting, and payment programs. CDC reports NHSN data to CMS on behalf of thousands of healthcare facilities that report to NHSN and participate in CMS's programs. In effect, NHSN serves as a multi-purpose platform that consolidates HAI and related reporting and analysis functions into one system, with a single set of data definitions, reporting specifications, and summary statistics. NHSN also is an extensible platform that enables coverage to be expanded, both by enrolling additional types of healthcare facilities, such as long term care facilities (LTCFs), and by adding or further specifying reportable event types, such as surgical site infections (SSIs) following operative procedures in ambulatory surgical centers (ASCs) and adverse reactions during or following administration of blood products. The revisions sought in this ICR are designed to (1) add surveillance and reporting coverage for LTCFs and ASCs, and (2) add or further specify a set of reportable events, specifically SSIs following procedures in ASCs, dialysis events, and Hemovigilance adverse reactions. In addition, clarifications were made on 46 data collections tools to incorporate changes in reporting volume influenced by CMS reporting requirements, as well as to add clarity to existing forms that aid a facility's understanding and completion of the questions.
- The intended uses of the resulting data are: estimate the magnitude of healthcare-associated infections (HAIs) and monitor HAI trends; facilitate interfacility and intrafacility comparisons with risk-adjusted data that can be used for local quality improvement activities; enable healthcare facilities to report HAI and prevention practice adherence data via NHSN to CMS in fulfillment of CMS's quality measurement programs for those data; and provide to state agencies, at their request, facility-specific NHSN patient safety component and healthcare personnel safety component adverse event and prevention practice adherence data for surveillance, prevention, or mandated public reporting.
- The data for NHSN are collected via a secure internet application.
- NHSN participation is open to all U.S, healthcare facilities.
- Reporting institutions are able to access their own data at any time and analyze it through the internet interface. Reports containing aggregated data are produced annually and posted on the NHSN website, http://www.cdc.gov/nhsn. The report is also published annually in a scientific journal to make NHSN data widely available. Other in-depth analysis of data from NHSN will be published in peer-reviewed journals and presented at scientific and professional meetings.

OMB No. 0920-0666
National Healthcare Safety Network (NHSN)
Revision Request, April 2017

The Centers for Disease Control and Prevention (CDC) is requesting 3-year approval of revisions to OMB Control No. 0920-0666: National Healthcare Safety Network. This collection is currently approved for 9,440,900 responses and 5,110,968 burden hours. This revision request includes the addition of 2 forms and revisions to 46 previously approved forms. The revisions being proposed in this ICR are designed to increase surveillance and reporting opportunities for specific types of facilities (i.e., Long-term Care facilities, Dialysis facilities, Non-acute care facilities) and event types (i.e., Surgical Site (SSI) events, Dialysis events, Hemovigilance component adverse reactions, and pediatric/adult ventilator-associated events). In addition, clarifications were made on many existing forms to provide facilities with greater clarity for completing optional and required questions and feedback from participating NHSN users. The reporting burden will increase by **464,498** hours, for a total estimated burden of **5,575,467** hours; annual cost of reporting would increase by **$14,716,728**.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Background

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920-0666. NHSN began as a voluntary surveillance system in 2005 and is managed by DHQP.. NHSN provides facilities, states, regions, and the nation with data needed to identify problem areas, measure progress of prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs). In addition, NHSN allows healthcare facilities to track blood safety errors and important healthcare process measures such as healthcare personnel influenza vaccine status and infection control adherence rates.

NHSN currently consists of five components: Patient Safety, Healthcare Personnel Safety, Biovigilance, Long-Term Care Facility, and Dialysis. One new component will be added to NHSN within the next year: Outpatient Procedure Component. In general, the data reported under the Patient Safety Component protocols are used to (1) determine the magnitude of the healthcare-associated adverse events under study and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices; and (2) to detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data will be used to describe the epidemiology of antimicrobial use and resistance and to understand the relationship of antimicrobial therapy to this growing problem. Under the Healthcare Personnel Safety Component protocols, data on events--both positive and adverse--are used to determine (1) the magnitude of adverse events in healthcare personnel, and (2) compliance with immunization and sharps injuries safety guidelines. Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are used to provide national estimates of adverse reactions and incidents. The Long-Term Care Facility (LTCF) Component more specifically and appropriately captures data from the residents of skilled nursing facilities. Reporting methods under this component have been

created by using forms from the Patient Safety Component as a base with modifications to specifically address the characteristics of LTCF residents and the needs of the facilities. The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities.

The Outpatient Procedure Component will be developed to gather data on the impact of infections and other outcomes related to outpatient procedures that are performed in settings such as Ambulatory Surgery Centers (ASCs), Hospital Outpatient Departments (HOPDs), and physicians' offices. Three event types will be monitored in this new component: Same Day Outcome Measures, Prophylactic Intravenous (IV) Antibiotic Timing, and Surgical Site Infections (SSI). The development of this component has been previously delayed to obtain additional user feedback and support from outside partners. This component is on track to be released in NHSN in 2018.

Since its launch, NHSN increasingly has served as the operational system for compliance with HAI reporting legislation established by states. As of March 2017, 35 states and the District of Columbia opted to use NHSN as their operational system for mandated reporting by healthcare facilities in their jurisdictions, with states having varied consequences for failing to use NHSN. Additionally, healthcare facilities in five U.S. territories including Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and Northern Mariana Islands are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

Data from NHSN are used for tracking of healthcare-associated infections and guides infection prevention activities that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance, and members of the public may use the data to select among available providers. Each of these parties relies on the completeness and accuracy of the data. CDC and CMS are fully committed to ensuring complete and accurate reporting, which is critical for protecting patients and guiding national, state, and local prevention priorities.

CMS collects HAI data and healthcare personnel influenza vaccination summary data on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs. Facilities that fail to successfully report quality measure data are potentially subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states with HAI reporting legislation, submit at least some HAI data to NHSN voluntarily.

NHSN's data collection tool updates continue to support the incentive programs managed by CMS. For example, survey questions have been added to support requirements for CMS' quality reporting programs. Additionally, CDC has partnered with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on the recruitment and retention of nursing homes reporting data to NHSN. This project has resulted in an increase in long term care facilities reporting to NHSN.

OMB most recently approved this request on 11/22/2016 for 5,110,966 burden hours. Approval of this revision request would result in a net increase of **464,498** burden hours. This

collection of information is authorized by the Public Health Service Act (42 USC 242b, 242k, and 242m(d)) (Attachment A).

The NHSN OMB revision, previously approved on November 2016, included 70 individual data collection forms; the current revision request includes revision of 46 of the previously approved forms. Revisions include edits to the annual cost burden for 14 previously approved forms, changes to 42 data collection forms, and the addition of 2 new forms for a total of 72 proposed data collection forms (Attachment C). A detailed explanation of the proposed program changes are provided in A15 of this document and Attachment D-1. An itemized list of proposed changes to each data collection form and their justifications are provided in Attachment D-2.

In summary, the proposed revisions to the information collection tools in NHSN include the following program changes with the associated change in time burden per individual hospital/facility per year:

1) There are multiple updates and clarifications made to 46 data collection forms in this request. In addition, the number of enrolled and participating facilities have increased and decreased since the previously approved revision for 14 data collections forms, which have been included in this revision. Many of the changes result in increases to burden/ cost estimates, while some do not require any changes to the burden. CDC needs these changes to be implemented due to further clarification of questions and response options to assist in user interpretation and correct completion of the forms. In addition, data collection tool updates assist incentive programs managed by partners at CMS. Questions have been added to support the CDC priority of prevention and surveillance of HAIs, continue to support Quality programs at CMS, and improve healthcare process measures. Questions that no longer meet the needs of CDC have been removed.

2) Changes were made to seven existing facility surveys, and one new facility survey was added to the Outpatient Procedure Component. Based on user feedback and internal reviews of the annual facility surveys, it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys such as informing Division of Healthcare Quality Promotion (DHQP) of nationwide infection control and antimicrobial stewardship practices within healthcare. In addition, the surveys are increasingly being used to analyze and interpret data elements reported into NHSN. Currently, surveys are used to appropriately risk-adjust the numerator and denominator data entered into NHSN while also guiding DHQP decisions on future division priorities for prevention. The addition of the new annual facility survey for the Outpatient Procedure Component (57.404) will expand and allow outpatient care facility types the opportunity to complete the NHSN facility-related survey. Specifically, this allows facilities to provide data on various identification methods, which will also inform decisions on risk adjustments. Facilities have reported being penalized for lacking precision in organism identification and have requested the utilization of advanced methodology (i.e., MALDI-TOF) to ensure data collection is accurate. The proposed changes will provide data that is sensible and will eliminate gaps in reporting. For example, without MALDI-TOF, two isolates from a blood culture would be identified as the same “coagulase-negative staph” organism and would not meet criteria for reporting a CLABSI. With MALDI-TOF, two separate organisms would be identified to the species

level, and a CLABSI would need to be reported. In addition, CDC has introduced a water management program to reduce the risk of Legionnaires'disease, which will add optional questions to four existing annual surveys. As a part of CDC's HAI prevention priorities, the water management program will provide CDC with data on prevention practices for Legionnaires' disease in facilities reporting to NHSN. Legionnaires' disease is on the rise in the United States, particularly in healthcare facilities, such as long-term care facilities, acute care, outpatient, and dialysis facilities. Legionella can become a serious health problem in building water systems when water is aerosolized and people inhale the droplets. To pose a health risk, Legionella first has to grow and be aerosolized so susceptible hosts (e.g., persons who are at least 50 years old, smokers, those with underlying medical conditions) can breathe in small, contaminated water droplets. There are several environmental factors that lead to Legionella growth, including biofilm, water temperature fluctuations, inadequate disinfectant, water stagnation, and scale and sediment. The purpose of the new survey questions are to enable the above specified facilities an opportunity to utilize NHSN as a resource for assessment and documentation of their specific policies and practices around water management.

57.103 – Patient Safety Component – Annual Hospital Survey: Increase of 5 minutes per hospital per year
57.137 – Long-Term Care Facility Component – Annual Facility Survey: Increase of 52 minutes per hospital per year
57.150 – Patient Safety Component – LTAC Annual Survey: Increase of 5 minutes per hospital per year
57.151 – Patient Safety Component – Rehab Annual Survey: Increase of 5 minutes per hospital per year
57.404 – Outpatient Procedure Component – Annual Facility Survey (New Form) Increase of 10 minutes per outpatient facility per year
57.500 – Outpatient Dialysis Center Practices Survey: Increase of 5 minutes per facility
57.507 – Home Dialysis Center Practices Survey: Increase of 5 minutes per facility

3) Eleven forms within the NHSN Patient Safety Component were revised to reflect the information that is conditionally required in denominator collection for Ventilator days when conducting PedVAE and Optional denominator collection for Patient days, Ventilator days, Episodes of Mechanical Ventilation (EMV) for gestational age categories. In addition, more fields are being made optional to collect APRV denominator days within each form. The number of reporting facilities using the patient safety forms 57.111, 57.115, 57.123, and 57.124 where decreased to reflect an actual number facilities reporting data into NHSN for a more accurate burden estimate.

57.111- Pneumonia (PNEU) Event: Participating facilities will decrease by approximately 4,200 facilities, decreasing annual cost burden
57.112 -Ventilator-Associated Event: Increase of 2 minutes per facility
57.113- Pediatric Ventilator-Associated Event: Participating facilities will decrease by approximately 1,900 facilities, Increase of 5 minutes per facility

57.114 - Urinary Tract Infection (UTI): No change in burden per hospital
57.115- Adult Sepsis Event: Participating facilities will decrease by approximately 1,400 facilities, decreasing annual cost burden
57.116- Denominators for Neonatal Intensive Care Unit (NICU): Increase of 1 hour per hospital per year
57.117- Denominators for Specialty Care Area (SCA)/Oncology (ONC): Increase of 2 minutes per facility
57.118-Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA): Increase of 2 minutes per facility
57.108 – Primary Bloodstream Infection (BSI): Increase of 3 minutes per facility
57.123- Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables; Participating facilities will decrease by approximately 5,650 facilities, decreasing annual cost burden
57.124- Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables; Participating facilities will decrease by approximately 5,200 facilities, decreasing annual cost burden

4) Fourteen Adverse Reaction forms within the Biovigilance Component were modified (57.307-57.320). The forms previously included required reaction-specific questions listed in one form (i.e., medical history, transfusion history, patient treatment history). Also, an 'Unknown' response option is added under the Patient Treatment Section of the Biovigilance Adverse Reaction Event on all 14 forms, which will eliminate recall bias for facilities. However, based on user feedback and internal reviews of the Adverse Reaction forms, there was a final decision made that questions and response options be amended to better align with the evolving usage of the adverse reaction forms.

57.307 – Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.308 – Hemovigilance Adverse Reaction - Allergic Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.309 – Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.310 – Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.311 – Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.312 – Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.313 – Hemovigilance Adverse Reaction – Infection: Decrease of 5 minutes per hospital per year
57.314 – Hemovigilance Adverse Reaction - Post Transfusion Purpura: Decrease of 5 minutes per hospital per year
57.315 – Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea: Decrease of 5 minutes per hospital per year
57.316 – Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease: Decrease of 5 minutes per hospital per year

57.317 – Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury: Decrease of 5 minutes per hospital per year
57.318 – Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload: Decrease of 5 minutes per hospital per year
57.319 – Hemovigilance Adverse Reaction - Unknown Transfusion Reaction: Decrease of 5 minutes per hospital per year
57.320 – Hemovigilance Adverse Reaction - Other Transfusion Reaction: Decrease of 5 minutes per hospital per year

5) Four forms were updated and two new forms were added to the Outpatient Safety Component of NHSN. The addition of the new forms (57.404, and 57.405), will allow NHSN to collect data and respond to public and professional interest in healthcare outcomes following surgical procedures in ambulatory surgery centers (ASCs), including SSIs and same day outcomes, such as wrong site surgery or transfers to hospitals. The forms are adapted from those used in the Patient Safety – SSI Protocol and intended for use by ASCs as part of a standardized, evidence-based surveillance program for identifying and tracking incidence and outcomes of HAIs in this unique patient care environment. Data collected from all OPC forms will be used by ASCs to identify areas where prevention of SSIs may be improved. Additional changes were made to the form names to better align with the information being collected in the forms (57.402, and 57.403).

57.400 – Outpatient Procedure Component - Annual Facility Survey: Increase of 5 minutes per facility
57.401 – Outpatient Procedure Component - Monthly Reporting Plan: Increase of 5 minutes per facility
57.402 – Outpatient Procedure Component Same Day Outcome Measures: Participating facilities will decrease by approximately 3,800 facilities, decreasing annual cost burden
57.403 – Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures: Participating facilities will decrease by approximately 3,800 facilities, decreasing annual cost burden
57.404 – Outpatient Procedure Component – Annual Facility Survey: (New Form) Increase of 10 minutes per hospital per year
57.405 – Outpatient Procedure Component - Surgical Site (SSI) Event: (New Form) Increase of 35 minutes per hospital per year

6) Seven LTCF forms will have an increase in the number of reporting facilities. Due to continued enrollment of facilities and increased participation and reporting of LTCF to NHSN, approximately 2,600 facilities will be reporting to NHSN by 2018. The increase in LTCFs is a result of CDC's work with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on the recruitment and retention of nursing homes collecting and reporting data into the NHSN in efforts to track and prevent *Clostridium difficile* infections. Recruitment and NHSN enrollment began in May 2016 and continues through July 2019.

57.137- Long-Term Care Facility Component – Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden
57.138- Laboratory-identified MDRO or CDI Event for LTCF: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden
57.139- MDRO and CDI LabID Event Reporting Monthly Summary Data for LTCF: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden
57.140- Urinary Tract Infection (UTI) for LTCF: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, Increase of 5 minutes per facility
57.141- Monthly Reporting Plan for LTCF: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden
47.142- Denominators for LTCF Locations: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden
47.143-Prevention Process Measures Monthly Monitoring for LTCF: Annual Facility Survey: Participating facilities will increase by approximately 2,250 facilities, increasing annual cost burden

7) Five Dialysis forms will have an increase in the number of reporting facilities. CDC is increasing the burden estimate for the number of facilities reporting to NHSN, due to the rise in facility enrollment and to account for future growth of the Dialysis Component.

57.500- Outpatient Dialysis Center Practices Survey: Participating facilities will increase by approximately 500 facilities, Increase of 5 minutes per facility
57.501- Dialysis Monthly Reporting Plan: Participating facilities will increase by approximately 500 facilities, increasing annual cost burden
57.502-Dialysis Event: Participating facilities will increase by approximately 500 facilities, increasing annual cost burden
57.503-Denominator for Outpatient Dialysis: Participating facilities will increase by approximately 500 facilities, increasing annual cost burden
57.504-Prevention Process Measures Monthly Monitoring for Dialysis: Participating facilities will increase by approximately 500 facilities, increasing annual cost burden

8) Two Dialysis forms will have a decrease in the number of reporting facilities. CDC is decreasing the burden estimate given that this form is optional and not required for Centers for Medicare and Medicaid Services (CMS) Quality Incentive Program (QIP).

57.507 – Home Dialysis Center Practices Survey: facilities decreased by 250 facilities, decreasing the annual cost burden per facility
57.125- Central Line Insertion Practices Adherence Monitoring: facilities decreased by 900 facilities, decreasing the annual cost burden per facility

2. <u>Purpose and Use of Information Collection</u>

The data collected under OMB Control No. 0920-0666 are used for:

- Estimation of the magnitude of healthcare-associated infections (HAIs)

- Monitoring of HAI trends
- Facilitation of interfacility and intrafacility comparisons with risk-adjusted data that can be used for local quality improvement activities
- Assistance to facilities in developing surveillance and analysis methods that permit timely recognition of patient safety problems and prompt intervention with appropriate measures.
- Development of clinical quality measures that can be used initially as internal benchmarks for healthcare facilities to measure their own performance and eventually—as a result of measure experience and measure enhancements or other changes as needed—as summary statistics that can be publicly reported for multiple healthcare facilities and serve as metrics for externally evaluating their care and incentivizing quality and patient safety.
- Comply with legal requirements – including but not limited to state or federal laws, regulations, or other requirements – for mandatory reporting of healthcare facility-specific adverse event, prevention practice adherence, and other public health data.
- Enable healthcare facilities to report HAI and prevention practice adherence data via NHSN to the Centers for Medicare and Medicaid Services (CMS) in fulfillment of CMS's quality measurement reporting programs including those data.
- Provide state and local departments of health with information that identifies the healthcare facilities in their state that participate in NHSN.
- Provide to state and local agencies, at their request, facility-specific, NHSN patient safety component and healthcare personnel safety component adverse event and prevention practice adherence data for surveillance, prevention, or mandatory public reporting.

NHSN is used to determine the magnitude of various healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures. The healthcare institutions participating in NHSN are required to collect data in an ongoing manner and report them monthly, seasonally, or yearly to CDC based on the specific data element being reported. NHSN provides facilities with risk-adjusted data that can be used for inter-facility comparisons and local quality improvement activities. CDC also assists facilities in developing surveillance and analysis methods that permit timely recognition of patient and healthcare personnel safety problems and prompt intervention with appropriate measures. Finally, facilities can conduct collaborative research with NHSN member facilities. For example, facilities can describe the epidemiology of emerging HAIs and pathogens, assess the importance of potential risk factors, further characterize HAI pathogens and their mechanism of resistance, and evaluate alternative surveillance and prevention strategies. In aggregate, CDC analyzes and publishes surveillance data annually to estimate and characterize the national burden of healthcare-associated infections. These publications can be accessed here: http://www.cdc.gov/nhsn/dataStat.html.

NHSN is also increasingly used to satisfy HAI reporting included in state legislation and local mandates. Thirty-five States and the District of Columbia have implemented HAI reporting using NHSN as the reporting mechanism, and more jurisdictions are expected in the coming years. In addition, CMS collects HAI data and healthcare personnel influenza vaccination summary data on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs. Facilities that fail to successfully report quality measure data are potentially subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. Facilities

report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS quality reporting programs to receive full payment.

Further, CDC DHQP is actively engaged with the CMS Center for Clinical Standards and Quality (CCSQ) in working to reduce healthcare associated infections and improve the quality of care within US healthcare facilities. Suggested revisions and enhancements for NHSN definitions and surveillance criteria are received from and vetted with NHSN users, as well as with external partners such as CMS CCSQ, the Healthcare Infection Control Practices Advisory Committee (HICPAC), and the Infectious Diseases Society of America (IDSA), as they are evaluated and developed by the internal CDC NHSN subject matter experts. Prior to CMS CCSQ adopting a new NHSN measure for requirement in a CMS Quality Reporting Program (QRP), they often require that the measure be endorsed by the National Quality Forum (NQF), therefore resulting in updates and improvements to NHSN forms as CDC strives to obtain the highest standard for measuring infection surveillance and process improvement. Further, changes to the number of respondents and responses per respondent for NHSN forms are directly related to the expansion of CMS QRPs. The CMS QRP final rules and a list of the NHSN forms used for the CMS QRPs and state mandated reporting can be found in Attachment E.

3. Use of Improved Information Technology and Burden Reduction

As stated in previous submissions to OMB, 100% of the data for NHSN are collected via a secure internet application. Only the minimum amount of information necessary for data collection is requested. Institutions that participate in NHSN are required to have a computer and Internet Service Provider (ISP), and they must provide the salaries of the data collectors and data entry personnel. These expenses would not exceed what is normally expended for a typical healthcare facility infection surveillance program. While the paper forms are provided for data collection, facilities are not required to use them for entry of data into NHSN.

Clinical Document Architecture (CDA) is a Health Level 7 (HL7) standard that provides a technical specifications for formatting electronic documents for purposes inter-operable data exchange and re-use. Currently, NHSN is able to accept data for the following event types/summary data via CDA:

- Central line-associated bloodstream infections (CLABSI)
- Catheter-associated urinary tract infections (CAUTI)
- Central line insertion practices (CLIP)
- Surgical site infections (SSI)
- Laboratory-identified (LabID) events
- Summary data for Intensive Care Units (ICU)/Other Locations (not NICU and SCA)
- Summary data for Neonatal Intensive Care Units (NICU)
- Summary data for Specialty Care Areas (SCA)
- Surgical procedures
- MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring
- Antimicrobial use (AU)
- Antimicrobial resistance events (AR)
- Antimicrobial resistance (AR) summary data
- Dialysis events
- Dialysis summary data

4. Efforts to Identify Duplication and Use of Similar Information

NHSN is the only modern national system that collects surveillance data on healthcare-associated infections, infection prevention process measure data, data on healthcare personnel safety measures such as blood and body fluid exposures and vaccination practices, and adverse events related to the transfusion of blood and blood products.

There are other organizations within the Department of Health and Human Services (HHS) (e.g., Patient Safety Task Force, the Health Resources and Services Administration, the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services) that work to improve patient safety and healthcare outcomes. In many cases, these agencies use the information generated from the NHSN to support their mission, and currently, the data collections do not overlap.

5. Impact on Small Businesses or Other Small Entities

There are several vendors, some of which may be considered small businesses, which sell data management tools with similar capabilities as NHSN. However, since NHSN is a voluntary system, facilities are free to choose a vendor product over NHSN. The exception is in those states that have mandated the use of NHSN for meeting their public reporting laws and in facilities that participate in the CMS Hospital Inpatient Quality Reporting Program, the CMS Prospective Payment System (PPS) End-stage Renal Disease (ESRD) Quality Incentive Program, CMS Inpatient Rehabilitation Facility Quality Reporting Program, CMS Inpatient Psychiatric Facility Quality Reporting Program, CMS Long Term Care Hospital Quality Reporting Program (LTCHQR), the CMS PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, and the CMS Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

However, in order to minimize any negative impact on vendors (i.e., loss of potential market share), CDC actively assists all vendors with facility data submission into NHSN.

6. Consequences of Collecting the Information Less Frequently

Many adverse events associated with healthcare, such as HAIs, occur in both endemic and epidemic patterns. It is in the best interest of the healthcare institution to conduct routine prospective surveillance in an ongoing manner to identify trends in endemic rates as well as outbreaks so that potential problems may be identified in a timely manner and appropriate measures instituted to minimize the number of affected patients or healthcare personnel. Collecting the data sporadically or less often than required by NHSN could potentially place patients at risk. In addition, CMS and state mandates require monthly reporting of HAI data via NHSN.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The healthcare institutions participating in NHSN are required to collect data in an ongoing manner and report them monthly to CDC. Such a schedule will not cause undue burden in most facilities, since data are usually collected daily or at least several times per week, and denominator data are tallied monthly. The data are usually entered into the computer at least monthly for a facility's analysis. Given these practices, it is advantageous to CDC to maintain a monthly reporting frequency. In NHSN, once the data are entered into the internet-based application, they are transmitted electronically to CDC with no additional data preparation.

As of March 2017, over 22,000 healthcare facilities participate in NHSN. Of these, there are over 3,700 acute care facilities; 6,600 outpatient dialysis facilities; 350 home dialysis; 550

long-term acute care facilities; 350 inpatient rehabilitation facilities; 700 inpatient psychiatric facilities; 2,500 long-term care facilities; and 4,800 ambulatory surgery facilities. The majority of these facilities are participating in CMS reporting programs for specific infection types. In 2011, the CMS Hospital Inpatient Quality Reporting Program began for all acute care facilities with intensive care units. Further, in 2013, the CMS Hospital Inpatient Quality Reporting Program expanded its requirements to include reporting of facility-wide inpatient (FacWideIN) Methicillin-Resistant Staphylococcus aureus (MRSA) blood specimen (Bacteremia) laboratory-identified (LabID) event data, facility-wide Inpatient (FacWideIN) Clostridium difficile infection (CDI) laboratory-identified (LabID) event data, and healthcare personnel (HCP) Influenza vaccination data. As very few acute care facilities opt out of these additional CMS reporting requirements, NHSN data are considered to be generalizable to all U.S. acute care facilities.

In 2012, CMS ESRD Quality Incentive Program was implemented for all dialysis facilities, therefore dialysis event data are considered to be generalizable to all outpatient dialysis facilities. Furthermore, CLABSI and CAUTI data from long-term acute care facilities, and CAUTI data from inpatient rehabilitation facilities, are considered generalizable to those facility and infection types as CMS reporting programs for those facility types went into effect in October 2012.

Further, because NHSN membership is now open to any healthcare facility and is increasingly being used to satisfy mandated reporting requirements at both the federal and state levels, we expect that over time the results will be more representative of all healthcare facility and infection types.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-Day Federal Register Notice was published in the *Federal Register* on 05/30/2017, Vol. 82, No.102, pg. 24711 (Attachment B). One non-substantive public comment was received (Attachment B2).

B. The Healthcare Infection Control Practices Advisory Committee (HICPAC) provides advice and guidance to the CDC Director and the Director of NCEZID regarding strategies for surveillance, prevention, and control of adverse events associated with healthcare in the United States. Committee members represent experts in the field of infection control. They are kept abreast of NHSN methodologies and results and proposed studies related to NHSN. The committee has the authority to make recommendations on the conduct of the surveillance systems and studies by DHQP.

Further, participating NHSN facilities are invited to make suggestions on how NHSN can help them more effectively use their own and national surveillance data. Many of the surveillance personnel in participating institutions are experts in the field of preventing adverse events such as hospital-associated infections and have extensive experience in the field. CDC personnel are available on a priority basis by e-mail to NHSN users. Member meetings for NHSN users are held each year in conjunction with annual professional meetings such as the International Conference of the Association for Professionals in Infection Control and Epidemiology (APIC) and the International Conference on Healthcare-Associated Infections.

In addition, DHQP actively interfaces with CMS and AHRQ as well as state health departments to ensure adequate but minimal data collection as well as effective data sharing

mechanisms to meet the purposes and surveillance needs of each agency using NHSN to operationalize HAI reporting mandates.

9. Explanation of Any Payment or Gift to Respondents

No monetary incentive is provided to NHSN participants.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by NCEZID who determined that the Privacy Act does not apply. The CDC Office of General Counsel (OGC) has also determined that the Privacy Act does not apply to this data collection. The CDC OGC believes that NHSN, as it is currently being utilized by CDC, is not a Privacy Act system of records and provides case law to support this determination (Henke v. U.S. Department of Commerce and Fisher v. NIH). Specifically, the OGC stated that "The CDC NHSN system is similar to the computerized information in both the Henke and Fisher cases. While CDC has the capability to retrieve data by personal identifier, CDC does not, as a matter of practice or policy, retrieve data in this way. Specifically, the primary practice and policy of CDC regarding NHSN data is to retrieve data by the name of the hospital or other non-personal identifier, not an individual patient, for surveillance and public health purposes. Furthermore, patient identifiers are not necessary for NHSN to operate, and CDC does not regularly or even frequently use patient names to obtain information about these individuals."

An Assurance of Confidentiality is granted for all data collected under NHSN. Accordingly, “the voluntarily provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with Sections 304, 306 and 308(d) of the Public Health Service Act (42 USC 242b, 242k, and 242m(d)).” (Attachment H) The NHSN Assurance of Confidentiality expires December 31, 2020.

The use of NHSN is both voluntary and mandated. State legislatures and some local health departments have mandated the use of NHSN for public reporting of healthcare-acquired infections by healthcare facilities in their jurisdiction.

While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures described in previous Section A.10 are still in effect. These include: use of a password issued via CDC’s Secure Access Management System for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

10.1 Privacy Impact Assessment Information

The surveillance data are typically obtained by designated and trained staff, primarily registered nurses in infection control or occupational health or transfusion medicine laboratory personnel who routinely access administrative and clinical services reports and medical records, make observations during ward and patient rounds, and verbally discuss patients' conditions with direct caregivers. Persons with training in other healthcare disciplines such as medical technology and microbiology also perform surveillance. Information on antibiotic resistance of clinical isolates and antimicrobial use is reported from the clinical laboratory and pharmacy, respectively. In most institutions, the data are recorded on hard-copy data collection forms and later entered into the NHSN web interface. However, approximately 6,800 NHSN facilities submit data electronically directly from a vendor system using Clinical Document Architecture (CDA).

Items of information to be collected include surveillance data related to various healthcare-associated adverse events and trends. Examples of these items are medical information and notes, medical records numbers, date of birth, gender, and biological specimen information. Personal identifying information is collected for one of two purposes. The information is used to either a) enumerate a specific event and minimize duplication (e.g., medical record number) and b) analyze risk factors related to the event data being collected (e.g., date of birth and gender). Data are reported to CDC, and CDC aggregates the data for national surveillance and public health practice evaluation purposes.

While the Privacy Act is not applicable, in accordance with the stringent safeguarding that must be in place for 308(d) assurance of confidentiality protected projects, all the safeguarding measures described in previous Section A.10 are still in effect. These include: use of a password issued via CDC's Secure Access Management System for access to the application; data encryption using Secure Socket Layer technology; and lastly, storage of data in password protected files on secure computers in locked, authorized-access-only rooms.

This data collection effort is consistent with the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA), which expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

For the participating healthcare institutions, data are collected in this system for the purposes of local surveillance and program evaluation. DHQP aggregates the data for national surveillance and public health practice evaluation purposes. No primary research will be conducted as part of this data collection effort, and no patient consent forms will be used. Although this is not a research project, this Protocol was submitted for ethical review to the CDC Institutional Review Board (IRB) and was approved (Protocol #4062, exp. 05/18/05.) The most recent request for amendment and continuation was approved on 08/29/06 and expired on 05/18/07. Subsequently, in consultation with NCEZID senior staff, the program was advised that the activities of the NHSN are surveillance and evaluation of public health practice and that IRB review is no longer required, therefore the protocol has been closed (Attachment F).

Justification for Sensitive Questions

The reporting of adverse events associated with healthcare can be sensitive unless the institution is assured that the data aggregating organization will provide security for the data and maintain the institution's confidentiality. As discussed in item A.10 above, NHSN is authorized to assure confidentiality to its participating individuals and institutions for voluntarily submitted data.

12. Estimates of Annualized Burden Hours and Costs

The tables below provide the burden hour and cost estimates for the proposed NHSN data collection tools. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

A. Estimates of Annualized Burden Hours

The tables below provide the burden hour and cost estimates for the proposed NHSN data collection tools. Many of the collection tools contained in NHSN are required to be completed for participation in NHSN, in a CMS reporting program, or in order to fulfill state reporting mandates. In order to estimate annualized burden hours and costs, the number of respondents is first determined by the number of facilities that report to NHSN by component and includes projected growth or reductions in facilities reporting during the ICR period. For forms that are required for participation in NHSN or a CMS reporting program, CDC calculates burden based on a 100 percent response rate, whereas an estimated response rate less than 100 percent is calculated for those forms that are voluntary or optional. CDC then considers the burden associated with surveillance, data entry, analysis, and validation to determine the amount of time required for each form to be completed. Annual labor rates reported by the U.S. Department of Labor are used to calculate the annual burden costs based on the hourly rate of pay for health professionals most qualified to complete NHSN data submission. Incorporating all proposed revisions, the estimated burden for reporting reflects an increase in hours by 464,498 hours and an increase in the burden cost by **$14,716,728** from the most recently-approved ICR in November 2016. Detailed revisions of the previous burden tables are available in Attachments D-3 and D-4.

Estimated annual burden[a]

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
57.100 NHSN Registration Form	2,000	1	5/60	167	Yes	This form must be completed during NHSN enrollment, which is required for CMS reporting
57.101 Facility Contact Information	2,000	1	10/60	333	Yes	This form must be completed during NHSN enrollment, which is required for CMS reporting
57.103 Patient Safety Component--Annual Hospital Survey	5,000	1	60/60	5,000	Yes; IQR, LTCHQR, PCHQR	
57.105 Group Contact Information	1,000	1	5/60	83	No	NHSN requires this form to be completed for NHSN group user registration
57.106 Patient Safety Monthly Reporting Plan	6,000	12	15/60	18,000	Yes; IQR, LTCHQR, PCHQR	
57.108 Primary Bloodstream Infection (BSI)	6,000	44	33/60	145,200	Yes; IQR, LTCHQR, PCHQR	
57.111 Pneumonia (PNEU)	1,800	72	30/60	64,800	No	This form must be completed for Pneumonia events reported into NHSN. The state of Pennsylvania has required reporting on

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
						this measure through NHSN by participating facilities in the state.
57.112 Ventilator-Associated Event	6,000	144	28/60	403,200	Yes; LTCHQR	
57.113 Pediatric Ventilator-Associated Event (PedVAE)	100	120	30/60	6,000	No	This form is not required, it is in the developmental stages and will be an active in 2019.
57.114 Urinary Tract Infection (UTI)	6,000	40	20/60	80,000	Yes; IQR PCHQR IRFQR LTCHQR	
57.115 Custom Event	600	91	35/60	31,850	No	This form is required by NHSN only when a facility customizes data for their event. This data is optional and for facility level analysis only.
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	6,000	12	4	288,000	Yes; IQR	
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	6,000	9	5.02	271,080	Yes; IQR	
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	6,000	60	5.02	1,807,200	Yes; IQR	
57.120 Surgical Site Infection (SSI)	6,000	36	35/60	126,000	Yes; IQR, PCHQR	
57.121 Denominator for Procedure	6,000	540	10/60	540,000	Yes; IQR, PCHQR	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	350	12	5/60	350	Yes; MU3	This form is required by NHSN for facilities that report data through electronic health records and as a part of the Meaningful Use Stage 3 incentive. The state of Missouri has a mandate which requires all facilities to report on AUR.
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	800	12	5/60	800	Yes; MU3	This form is required by NHSN for facilities that report data through electronic health records and as a part of MU3. The state of Missouri has a mandate which requires all facilities to report on AUR.
57.125 Central Line Insertion Practices Adherence Monitoring	100	100	25/60	4,167	No	
57.126 MDRO or CDI Infection Form	6,000	72	30/60	216,000	Yes; IQR, LTCHQR, IRFQR, PCHQR	
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	6,000	24	15/60	36,000	Yes; IQR, LTCHQR, IRFQR, PCHQR	
57.128 Laboratory-identified MDRO or CDI Event	6,000	240	20/60	480,000	Yes; IQR, LTCHQR,	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
					IRFQR, PCHQR	
57.129 Adult Sepsis	50	250	25/60	5,208	No	This form is not required by NHSN; this module is in a developmental phase and is expected to be active by 2020
57.137 Long-Term Care Facility Component – Annual Facility Survey	2,600	1	2	5,200	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.138 Laboratory-identified MDRO or CDI Event for LTCF	2,600	12	20/60	10,400	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
						Facilities report data to NHSN.
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	10/60	5,200	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.140 Urinary Tract Infection (UTI) for LTCF	2,600	14	35/60	21,233	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.141 Monthly Reporting Plan for LTCF	2,600	12	5/60	2,600	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
						National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.142 Denominators for LTCF Locations	2,600	12	4	124,800	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections. The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	12	5/60	600	No	This form is required by NHSN for facilities that voluntarily report data into NHSN's National Nursing Home Quality Collaborative with CMS to track and prevent Clostridium difficile infections.

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
						The state of Nevada has mandated that all Skilled Nursing Facilities report data to NHSN.
57.150 LTAC Annual Survey	400	1	60/60	400	Yes; LTCHQR	
57.151 Rehab Annual Survey	1,000	1	60/60	1000	Yes; IRFQR	
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	8	400	No	This form is required by NHSN and optional for facilities to report various HPS events
57.203 Healthcare Personnel Safety Monthly Reporting Plan	17,000	1	5/60	1,417	Yes; IPFQR, PCHQR, ASCQR, IRFQR, LTCHQR, OQR, ESRD QIP	
57.204 Healthcare Worker Demographic Data	50	200	20/60	3,333	No	
57.205 Exposure to Blood/Body Fluids	50	50	1	2,500	No	
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60	375	No	
57.207 Follow-Up Laboratory Testing	50	50	15/60	625	No	
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60	417	No	
57.300 Hemovigilance Module Annual Survey	500	1	2	1,000	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.301 Hemovigilance Module Monthly	500	12	1/60	100	No	This form is required by

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
Reporting Plan						NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	1.17	7,020	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.305 Hemovigilance Incident	500	10	10/60	833	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.306 Hemovigilance Module Annual Survey - Non-acute care facility	200	1	35/60	117	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	500	4	20/60	667	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.308 Hemovigilance Adverse Reaction -	500	4	20/60	667	No	This form is required by

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
Allergic Transfusion Reaction						NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	500	2	20/60	333	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	500	4	20/60	667	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.313 Hemovigilance Adverse Reaction -	500	1	20/60	167	No	This form is required by

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
Infection						NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.318 Hemovigilance Adverse Reaction -	500	2	20/60	333	No	This form is required by

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
Transfusion Associated Circulatory Overload						NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	500	1	20/60	167	No	This form is required by NHSN and optional for facilities to report Biovigilance Component (BV) events. The state of Massachusetts mandates reporting BV events into NHSN.
57.400 Outpatient Procedure Component—Annual Facility Survey	5000	1	10/60	833	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 35 states that have SSI reporting mandates.
57.401 Outpatient Procedure Component - Monthly Reporting Plan	5000	12	20/60	20,000	No	This form is required for Ambulatory Surgery Centers

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
						(ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 35 states that have SSI reporting mandates.
57.402 Outpatient Procedure Component Same Day Outcome Measures	1,200	25	40/60	20,000	No	This form is optional for reporting into NHSN
57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	1,200	12	40/60	9,600	No	This form is optional for reporting into NHSN
57.404 Outpatient Procedure Component – SSI Denominator	5000	540	10/60	450,000	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 35 states that have SSI reporting mandates.
57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	5000	36	35/60	105,000	No	This form is required for Ambulatory Surgery Centers (ASC) that have state-based surgical site infection (SSI) surveillance reporting mandates. There are 35 states that have SSI reporting mandates.
57.500 Outpatient Dialysis Center Practices Survey	7,000	1	2.05	14,350	Yes; ESRD QIP	
57.501 Dialysis Monthly Reporting Plan	7,000	12	5/60	7,000	Yes;	

Form Number & Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (Hours)	Total Burden (Hours)	Required by a CMS Reporting program	Requirement for NHSN participation or state reporting
					ESRD QIP	
57.502 Dialysis Event	7,000	60	25/60	175,000	Yes; ESRD QIP	
57.503 Denominator for Outpatient Dialysis	7,000	12	10/60	14,000	Yes; ESRD QIP	
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	2,000	12	1.25	30,000	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN
57.505 Dialysis Patient Influenza Vaccination	325	75	10/60	4,063	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN
57.506 Dialysis Patient Influenza Vaccination Denominator	325	5	10/60	271	No	This form is required by NHSN only when a dialysis facility reports flu data into NHSN
57.507 Home Dialysis Center Practices Survey	350	1	30/60	175	Yes; ESRD QIP	
	Total Estimated Annual Burden (Hours)			**5,575,467**		

[a] Columns may not total due to rounding.

CMS Program Definitions:
End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) - ESRD QIP
Hospital Inpatient Quality Reporting Program - IQR
Hospital Outpatient Quality Reporting Program - OQR
Long Term Care Hospital* Quality Reporting Program - LTCHQR
Inpatient Rehabilitation Facility Quality Reporting Program - IRFQR
Ambulatory Surgery Centers Quality Reporting Program - ASCQR
PPS-Exempt Cancer Hospital Quality Reporting Program - PCHQR
Inpatient Psychiatric Facility Quality Reporting Program - IPFQR
Meaningful Use Stage 3- MU3

B. Estimates of Annualized Costs

The average salary of the professional discipline that is expected to perform surveillance has been used in the calculations of burden and is based on data from the Department of Labor, Bureau of Labor & Statistics, 2015. Those most likely to complete this surveillance are health practitioners at a mid (50th percentile average wage) or senior (75th percentile average wage) level. Those personnel and their estimated hourly wages are shown below.

2015 Department Of Labor Salary Estimates		
Professional Labor Category	**Percentile**	**Hourly Wage**
Infection Preventionist RN	75th	$39.66
Medical/Clinical Laboratory Technologist	75th	$34.99
Occupational Health Nurse	50th	$33.75
Pharmacist	50th	$58.41
Staff RN	50th	$32.45
Laboratory Technician	50th	$18.73

http://www.bls.gov/bls/blswage.htm#National
Accessed: 3/11/2017

Estimated annualized burden cost[a]

Type of Respondents	**Form Number & Name**	**Total Burden (Hours)**	**Hourly Wage Rate**	**Total Respondent Costs**
Registered Nurse (Infection Preventionist)	57.100 NHSN Registration Form	167	$39.66	$6,610
Registered Nurse (Infection Preventionist)	57.101 Facility Contact Information	333	$39.66	$13,220
Registered Nurse (Infection Preventionist)	57.103 Patient Safety Component--Annual Hospital Survey	5,000	$39.66	$198,300
Registered Nurse (Infection Preventionist)	57.105 Group Contact Information	83	$39.66	$3,305
Registered Nurse (Infection Preventionist)	57.106 Patient Safety Monthly Reporting Plan	18,000	$39.66	$713,880
Registered Nurse (Infection Preventionist)	57.108 Primary Bloodstream Infection (BSI)	145,200	$39.66	$5,235,120
Registered Nurse (Infection Preventionist)	57.111 Pneumonia (PNEU)	64,800	$39.66	$2,569,968
Registered Nurse (Infection Preventionist)	57.112 Ventilator-Associated Event	403,200	$39.66	$15,990,912
Registered Nurse (Infection Preventionist)	57.113 Pediatric Ventilator-Associated Event (PedVAE)	6,000	$39.66	$237,960
Registered Nurse (Infection Preventionist)	57.114 Urinary Tract Infection (UTI)	80,000	$39.66	$3,172,800
Registered Nurse (Infection Preventionist)	57.115 Custom Event	31,850	$39.66	$1,263,171
Staff RN	57.116 Denominators for Neonatal Intensive Care Unit (NICU)	288,000	$32.45	$9,345,600
Staff RN	57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	271,080	$32.45	$8,796,546
Staff RN	57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	1,807,200	$32.45	$58,643,640

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Registered Nurse (Infection Preventionist)	57.120 Surgical Site Infection (SSI)	126,000	$39.66	$4,997,160
Staff RN	57.121 Denominator for Procedure	540,000	$32.45	$17,523,000
Laboratory Technician	57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	350	$18.73	$6,556
Pharmacist	57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	800	$58.41	$46,728
Registered Nurse (Infection Preventionist)	57.125 Central Line Insertion Practices Adherence Monitoring	4,167	$39.66	$165,250
Registered Nurse (Infection Preventionist)	57.126 MDRO or CDI Infection Form	216,000	$39.66	$8,566,560
Registered Nurse (Infection Preventionist)	57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	36,000	$39.66	$1,427,760
Registered Nurse (Infection Preventionist)	57.128 Laboratory-identified MDRO or CDI Event	480,000	$39.66	$19,036,800
Registered Nurse (Infection Preventionist)	57.129 Adult Sepsis	5,208	$39.66	$206,563
Registered Nurse (Infection Preventionist)	57.137 Long-Term Care Facility Component – Annual Facility Survey	5,200	$39.66	$206,232
Registered Nurse (Infection Preventionist)	57.138 Laboratory-identified MDRO or CDI Event for LTCF	10,400	$39.66	$412,464
Registered Nurse (Infection Preventionist)	57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	5,200	$39.66	$206,232
Registered Nurse (Infection Preventionist)	57.140 Urinary Tract Infection (UTI) for LTCF	21,233	$39.66	$842,114
Registered Nurse (Infection Preventionist)	57.141 Monthly Reporting Plan for LTCF	2,600	$39.66	$103,116
Registered Nurse (Infection Preventionist)	57.142 Denominators for LTCF Locations	128,800	$39.66	$4,949,568
Registered Nurse (Infection Preventionist)	57.143 Prevention Process Measures Monthly Monitoring for LTCF	2,600	$39.66	$103,116
Registered Nurse (Infection Preventionist)	57.150 LTAC Annual Survey	400	$39.66	$15,864
Registered Nurse (Infection Preventionist)	57.151 Rehab Annual Survey	1000	$39.66	$39,660
Occupational Health RN/Specialist	57.200 Healthcare Personnel Safety Component Annual Facility Survey	400	$33.75	$13,500
Occupational Health RN/Specialist	57.203 Healthcare Personnel Safety Monthly Reporting Plan	1,417	$33.75	$47,813
Occupational Health RN/Specialist	57.204 Healthcare Worker Demographic Data	3,333	$33.75	$112,500
Occupational Health RN/Specialist	57.205 Exposure to Blood/Body Fluids	2,500	$33.75	$84,375
Occupational Health RN/Specialist	57.206 Healthcare Worker Prophylaxis/Treatment	375	$33.75	$12,656
Laboratory Technician	57.207 Follow-Up Laboratory Testing	625	$18.73	$11,706
Occupational Health RN/Specialist	57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	417	$33.75	$14,063
Medical/Clinical Laboratory Technologist	57.300 Hemovigilance Module Annual Survey	1,000	$34.99	$34,990

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
Medical/Clinical Laboratory Technologist	57.301 Hemovigilance Module Monthly Reporting Plan	100	$34.99	$3,499
Medical/Clinical Laboratory Technologist	57.303 Hemovigilance Module Monthly Reporting Denominators	7,020	$34.99	$245,630
Medical/Clinical Laboratory Technologist	57.305 Hemovigilance Incident	833	$34.99	$29,158
Medical/Clinical Laboratory Technologist	57.306 Hemovigilance Module Annual Survey - Non-acute care facility	117	$34.99	$4,082
Medical/Clinical Laboratory Technologist	57.307 Hemovigilance Adverse Reaction - Acute Hemolytic Transfusion Reaction	667	$34.99	$23,327
Medical/Clinical Laboratory Technologist	57.308 Hemovigilance Adverse Reaction - Allergic Transfusion Reaction	667	$34.99	$23,327
Medical/Clinical Laboratory Technologist	57.309 Hemovigilance Adverse Reaction - Delayed Hemolytic Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.310 Hemovigilance Adverse Reaction - Delayed Serologic Transfusion Reaction	333	$34.99	$11,663
Medical/Clinical Laboratory Technologist	57.311 Hemovigilance Adverse Reaction - Febrile Non-hemolytic Transfusion Reaction	667	$34.99	$29,158
Medical/Clinical Laboratory Technologist	57.312 Hemovigilance Adverse Reaction - Hypotensive Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.313 Hemovigilance Adverse Reaction – Infection	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.314 Hemovigilance Adverse Reaction - Post Transfusion Purpura	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.315 Hemovigilance Adverse Reaction - Transfusion Associated Dyspnea	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.316 Hemovigilance Adverse Reaction - Transfusion Associated Graft vs. Host Disease	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.317 Hemovigilance Adverse Reaction - Transfusion Related Acute Lung Injury	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.318 Hemovigilance Adverse Reaction - Transfusion Associated Circulatory Overload	333	$34.99	$11,663
Medical/Clinical Laboratory Technologist	57.319 Hemovigilance Adverse Reaction - Unknown Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.320 Hemovigilance Adverse Reaction - Other Transfusion Reaction	167	$34.99	$5,832
Medical/Clinical Laboratory Technologist	57.400 Outpatient Procedure Component— Annual Facility Survey	833	$32.45	$27,042
Staff RN	57.401 Outpatient Procedure Component - Monthly Reporting Plan	20000	$32.45	$649,000
Staff RN	57.402 Outpatient Procedure Component Same Day Outcome Measures	20,000	$32.45	$649,000
Staff RN	57.403 Outpatient Procedure Component - Monthly Denominators for Same Day Outcome Measures	9,600	$32.45	$311,520
Staff RN	57.404 Outpatient Procedure Component - SSI Denominator	450,000	$39.66	$14,602,500
Registered Nurse (Infection Preventionist)	57.405 Outpatient Procedure Component - Surgical Site (SSI) Event	105,000	$32.45	$4,164,300
Staff RN	57.500 Outpatient Dialysis Center Practices Survey	14,350	$39.66	$569,121
Registered Nurse	57.501 Dialysis Monthly Reporting Plan	7,000	$32.45	$227,150

Type of Respondents	Form Number & Name	Total Burden (Hours)	Hourly Wage Rate	Total Respondent Costs
(Infection Preventionist)				
Staff RN	57.502 Dialysis Event	175,000	$32.45	$5,678,750
Staff RN	57.503 Denominator for Outpatient Dialysis	14,000	$32.45	$454,300
Staff RN	57.504 Prevention Process Measures Monthly Monitoring for Dialysis	30,000	$32.45	$973,500
Staff RN	57.505 Dialysis Patient Influenza Vaccination	4,063	$32.45	$131,828
Staff RN	57.506 Dialysis Patient Influenza Vaccination Denominator	271	$32.45	$8,789
Staff RN	57.507 Home Dialysis Center Practices Survey	175	$39.66	$6,941
		Total Estimated Cost		$194,782,795

[a] Columns and rows may not total due to rounding.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There is no change in the estimates of annual cost burden to respondents. Capital and start-up cost: Healthcare institutions participating in NHSN are responsible for choosing the specific computer brand and model to purchase. Minimum system requirements are as follows: 3 GHz processor – Intel Pentium IV or AMD K6/Athlon/Duron family or compatible processor; 512 MB of RAM; sound card; speakers or headphones; hard disk minimum 40 GB; Microsoft Internet Explorer 7 or higher; 17" Super VGA (800 X 600) or higher resolution video adaptor and monitor; Windows XP, Windows 2000, Windows Vista, or Windows 7 Operating system; laser printer; high-speed internet access >200 Kbs (e.g., T1, cable, DSL or ADSL); and e-mail account. It is expected that most institutions will have met or exceeded these recommendations for other business purposes. Recurring costs: Healthcare facilities participating in NHSN must have access to high-speed Internet, which most have for other business purposes. No other recurring costs are anticipated.

14. Annualized Cost to the Government

A total of 153 FTE/contractor personnel are actively involved in the enhancement and maintenance of NHSN. The estimated cost to the government of this OMB revision of NHSN is based on expenses incurred in the following categories: personnel and programming contracts. The items and their costs relevant to the proposed modifications to NHSN are shown in the table below. The total cost to the government in 2018 is estimated to be $17,050,666.

NHSN Estimated Annual Cost to the Government

Expense Item	Description		Estimated Annual Cost
Personnel	The personnel categories and their FTE contributions are as follows:		FTE annual compensation in FY 2017 will be $3,563,758
	Supervisory. Medical Officer	1	
	Medical Epidemiologist	2	
	Statistician	2	
	Epidemiologist	8	
	Nurse Epidemiologist	2	
	Systems Analyst	3	
	Public Health Analyst	2	

Expense Item	Description		Estimated Annual Cost
	Computer Scientist	3	
Programming contracts	Design, develop, and deploy enhancements to NHSN		$13,486,908
Total			**$17,050,666**

15. Explanation for Program Changes or Adjustments

Forty-six previously approved data collection tools under OMB No. 0920-0666 have been revised in this revision request. More specifically, forms are being revised to improve data collection. NHSN has experienced growth and an increase and decrease in some of its reporting facilities, and two forms are being added to this package. Proposed program changes are explained below.

1) Significant updates to annual facility surveys (57.103, 57.137, 57,404, 57.500, and 57.507)

Justification: Based on user feedback and internal reviews of the annual facility surveys, it was determined that questions and response options be amended, removed, or added to fit the evolving uses of the annual facility surveys. The surveys are being increasingly used to help intelligently interpret the other data elements reported into NHSN. Currently the surveys are used to appropriately risk-adjust the numerator and denominator data entered into NHSN while also guiding DHQP decisions on future division priorities for prevention.

2) Outpatient Procedure Component will be updating four data collection forms and adding two new forms to NHSN (57.400, 57.401, 57.402, 57.403, and 57.404)

Justification: The addition of these forms will allow NHSN to collect data amid increasing interest in the public health impact of SSIs in Ambulatory Surgery Center (ASC) environment. The forms are adapted from those used in the Patient Safety – SSI Protocol and intended for use by ASCs as part of a standardized, evidence-based surveillance program for identifying and tracking incidence and outcomes of healthcare-associated infections in this unique patient care environment. Data collected by use of these forms may be used by ASCs to identify areas where prevention of SSIs may be improved. Additional changes were made to the form names to better align with the information being collected in the forms.

3) Fourteen adverse reaction forms were updated in the Hemovigilance Module (57.307, 57.308, 57.309, 57.310, 57.311, 57.312, 57.313, 57.314, 57.315, 57.316, 57.317, 57.318, 57.319, 57.320)

Justification: Medical History questions on all 14 forms are optional to report, and sub-questions for Transfusion History and Patient Treatment sections are now optional. Also, an 'Unknown' response option is added under the Patient Treatment Section of the Biovigilance Adverse Reaction Event on all 14 forms, which will eliminate recall bias for facilities. Based on user feedback, there was more time requested to acclimate to newly required fields. CDC opted to change the new fields from required to optional. This will allow for more robust data collection to identify emerging trends in transfusion-related adverse events among these facilities.

4) Eleven forms were revised in the Patient Safety Component (57.108, 57.112, 57.111, 57.113, 57.114, 57.115, 57.123, 57.124, 57.116, 57.117, and 57.118)

Justification: Revisions were made to reflect the information that is conditionally required in denominator collection for Ventilator days when conducting PedVAE and Optional denominator collection for Patient days, Ventilator days, and Episodes of Mechanical Ventilation (EMV) for gestational age categories. In addition, more fields are being made optional to collect APRV denominator days within each form. The number of reporting facilities using the patient safety forms 57.111, 57.115, 57.123, and 57.124 where decreased to reflect an actual number facilities reporting data into NHSN for a more accurate burden estimate.

5) All other NHSN data collection form revisions.

Justification: A number of minor revisions, updates, and clarifications have been made to 38 NHSN data collection forms. See Attachment D-2 for itemized NHSN data collection forms revisions and justifications. Resulting burden revisions are itemized in Attachments D-3 and D-4.

16. Plans for Tabulation and Publication and Project Time Schedule

NHSN is an ongoing data collection system and as such does not have an annual timeline. The data are reported on a continuous basis by participating institutions and aggregated by CDC into a national database that is analyzed for two main purposes: to describe the epidemiology of healthcare-associated adverse events, and to provide comparative data for populations with similar risks. Comparative data can be used by participating and also by non-participating healthcare institutions that collect their data using NHSN methodology.

The reporting institutions will be able to access their own data at any time and analyze them through the internet interface. Reports containing aggregated data will be produced annually and posted on the NHSN website, http://www.cdc.gov/nhsn. The report is also published annually in a scientific journal to make NHSN data widely available. Other in-depth analysis of data from NHSN will be published in peer-reviewed journals and presented at scientific and professional meetings. The proposed modifications to NHSN will not alter the plans for tabulation, publication, nor the time schedule.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.