Supporting Statement – Part A
Quality Measures and Procedures for Hospital Reporting of Quality Data for the FY 2015 IPPS Annual Payment Update

A. Background

CMS seeks to empower consumers to make more informed decisions about their health care, and to promote higher quality of care through its quality reporting programs. The Hospital Inpatient Quality Reporting (IQR) program was first established to implement section 5001(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173), which authorized CMS to pay hospitals that successfully reported quality measures a higher annual update to their payment rates. It builds on a voluntary Inpatient Quality Reporting program which remains in effect. The Hospital IQR program formerly known as the Reporting Hospital Quality Data for Annual Payment Update program, began with an initial set of 10 measures. Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) revised the mechanism used to update the standardized amount for payment for hospital inpatient operating costs. This is reflected in Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act which provide that the annual payment update (APU) will be reduced for any "subsection (d) hospital" that does not submit certain quality data in a form and manner, and at a time, specified by the Secretary.

Section 5001(a) of the DRA also expanded the scope of IQR, requiring CMS to add new measures. Sections 1886(b)(3)(B)(viii)(III) through (V) of the Social Security Act, required CMS to "adopt the baseline set of performance measures as set forth in the November 2005 report by the Institute of Medicine of the National Academy of Sciences", instructed the Secretary to "add other measures that reflect consensus among affected parties", and allowed the Secretary to "replace any measures or indicators in appropriate cases". When adding new measures, the law required CMS when "feasible and practical" to select measures put forward by "one or more national consensus building entities".

Many provisions of the Affordable Care Act (ACA) drove further additions to these measure sets, and by linking IQR data to value-based purchasing, the ACA increased both the importance of IQR data and the need for a broad range of indicators. Section 3013 of the Affordable Care Act (ACA) modified Section 931 of the Public Health Service Act by requiring CMS "identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating or expansion". Section 3025 of the ACA amended Section 1886(q)(8)(C)(i) of the Social Security Act to require public reporting of readmission rates and to require subsection (d) hospitals to submit all data that CMS determines it needs to calculate and publicly report readmission rates.

Section 3001 of the Affordable Care Act of 2010 modified Section 1886(o) of the Social Security Act to mandate CMS' transition from a passive supplier of healthcare to an active purchaser of quality care. According to Section 1886(o)(2)(A) of the Social Security Act, CMS must select measures for Value-Based Purchasing (VBP) from among measures (other than measures of admissions) in the Hospital IQR program. Consistent with this legislation, CMS established a Hospital VBP program in 2011 which qualifies hospitals for monetary incentives based on their performance on a defined set of quality measures reported under the Hospital IQR program. The proposed FY 2013 IPPS includes data from the following topic areas in the 2015 VBP payment determination: (a) processes of clinical care for acute myocardial infarction, heart failure, pneumonia, and surgical patients; (b) health care-associated infections (HAI); (c) patient safety indicators (PSI) from the Agency for Healthcare Quality and Research (AHRQ) measurement set; (d) consumer data from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey; and (e) cost efficiency measures.

Section 3014 of the ACA modified Section 1890(b) of the Social Security Act to require CMS to develop quality and efficiency measures through a "consensus-based entity". Consequently, the Measure Applications Partnership (MAP) was formed to develop measures consistent with these requirements. MAP is convened by the National Quality Forum (NQF). It's organizational members include the American Association of Retired Persons, America's Health Insurance Plans, the American Federation of Labor- Congress of Industrial Organizations, the American Hospital Association, the American Medical Association, the American Nurses Association, the Federation of American Hospitals, and the Pacific Business Group on Health. Nationally recognized subject matter experts are also voting members of MAP. CMS consulted with the MAP and received its formal recommendations before identifying IQR measures to be included in the FY 2013 IPPS proposed rule. The proposed rule also includes some measures and measure sets that were finalized for adoption for the 2015 APU determination in previous years. For example, the adoption of the stroke measure set for the 2015 APU determination was finalized in the FY 2012 IPPS rule. To adopt measures prior to the formation of MAP, CMS collaborated with the Hospital Quality Alliance (HQA). HQA, was an industry-led group formed to promote voluntary hospital quality improvement and public reporting of hospital quality information. It disbanded in December 2011.

B. New IQR Quality Measure Sets and Measures

1. Introduction

The 2015 APU determination will be based on IQR data reported and supporting forms submitted by hospitals between January 2013 and May 2014. The FY 2013 IPPS proposed rule recommends the collection of 59 measures to be used for the FY 2015 APU. It recommends suspension of an additional 17 measures. Because one or more of the measures proposed for suspension may be reinstated

during the public comment period, 76 measures in 19 measure sets are included in this package. In an effort to reduce burden, a variety of different data collection mechanisms are employed, with every consideration taken to employ data and data collection systems already in place. Therefore, a complete list of measures and other data collection forms are organized according to type of data collected and data collection mechanism and are included in Appendix Tables 1-4. New chart-abstracted measure sets and new measures added to exsiting measure sets are listed in section 2. New measure sets based on administrative data are described in section 3. New measure sets employing other data collection mechanisms are described in section 4. New forms to support the general reporting process are described in section 5.

2. New Measure Sets

2.1 New chart-abstracted measure sets

Emergency Department (ED) Throughput: 2 measures

- ED-1 Median time from ED arrival to ED departure for admitted ED patients
- ED-2 Admit decision time to ED departure time for admitted patients

Global immunization (IMM): 2 measures

- IMM-1 Pneumonia immunization
- IMM-2 Influenza immunization

Perinatal Care (PC): 1 measure

- PC-01 Elective Delivery Prior to 39 Completed Weeks Gestation

Stroke (STK): 8 measures

- STK-1 - Venous thromboembolism (VTE) prophylaxis
- STK-2 – Ischemic stroke patients discharged on antithrombotic therapy
- STK-3 – Anticoagulation therapy for atrial fibrillation/flutter
- STK-4 - Thrombolytic therapy for acute ischemic stroke patients
- STK-5 - Antithrombotic therapy by end of hospital day 2
- STK-6 - Discharged on statin medication
- STK-8 - Stroke education
- STK-10 - Assessed for rehabilitation services

Venous Thromboembolism (VTE): 6 measures

- VTE-1 - VTE prophylaxis
- VTE-2 - Intensive care unit venous thromboembolism prophylaxis
- VTE-3 - VTE patients with anticoagulation overlap therapy
- VTE-4 - VTE patients receiving unfractionated Heparin with dosages/platelet count monitoring by protocol
- VTE-5 – VTE discharge instructions
- VTE-6 - Incidence of potentially-preventable VTE

2.2 New measures added to existing chart-abstracted measure sets

Acute myocardial infarction (AMI): 1 new measure out of 4 measures

- AMI-10 Statin prescribed at discharge
- +3 ongoing measures

Surgical Care Improvement Project (SCIP): 4 new measures out of 9 measures

- SCIP-INF-04 Cardiac surgery patients with controlled 6AM postoperative serum glucose
- SCIP-INF-09 Urinary catheter removed on postoperative day 1 or postoperative day 2 with day of surgery being day zero
- SCIP-INF-10 Surgery patients preoperative temperature management
- SCIP Cardiovascular-2 Surgery patients on Beta-blocker therapy prior to arrival who received a Beta-blocker during perioperative period
- + 5 ongoing measures

3. New measure sets derived through secondary data analysis of administrative data

AHRQ Patient Safety Indicators (PSI), Inpatient Quality Indicators (IQI) and Composites:

9 measures

- PSI 06 Iatrogenic pneumothorax
- PSI 11: Post-operative respiratory failure
- PSI 12: Post Operative pulmonary embolism or deep vein thrombosis
- PSI 14 Postoperative wound dehiscence in abdominopelvic surgical patients
- PSI 15 Accidental puncture or laceration
- PSI 90 Complication/patient safety for selected indicators (composite)
- IQI 11 Abdominal aortic aneurysm (AAA) repair mortality rate (with or without volume)
- IQI 19 Hip fracture mortality rate
- IQI 91 Mortality for selected medical conditions (composite)

AHRQ Patient Safety Indicators (PSIs) for Nursing Sensitive Care (NSC): 1 measure

- PSI 04 Death among surgical inpatients with serious treatable complications

Cost efficiency (CE): 1 measure

- Medicare spending per beneficiary

Hospital Acquired Conditions (HAC): 8 measures

- Air embolism
- Blood incompatibility
- Catheter-associated urinary tract infection

- Falls and trauma: (includes fracture dislocation, intracranial injury, crushing injury, burn, electric shock)
- Foreign object retained after surgery
- Manifestations of poor glycemic control
- Pressure ulcer stages 3 or 4
- Vascular catheter associated infections

Readmissions (READM): 7 measures

- READM-30-AMI 30-day all-cause risk-standardized readmission rate following acute
- myocardial infarction (AMI) hospitalization
- READM-30-HF 30-day all-cause risk standardized readmission rate following heart failure (HF) hospitalization
- READM-30-PN 30-day all-cause risk standardized readmission rate following pneumonia (PN) hospitalization
- READM-30-HKR 30 day all-cause risk standardized readmission rate following hip/knee
- replacement (HKR) hospitalization.
- READM-30-HWR 30 day all-cause risk standardized hospital-wide unplanned readmission rate

Surgical Care (claims-based) (1 measure)

- Hip/knee complication - Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA)

4. New measure sets obtained through other data collection mechanisms

Healthcare Associated Infections (HAI): 6 measures

- Catheter associated urinary tract infection (CAUTI)
- Central line-associated bloodstream infection (CLABSI)
- Methicillin-resistant Staphylococcus aureus (MRSA) bacteremia
- Clostridium difficile (CDI)
- Influenza vaccination for healthcare personnel
- Surgical site infections (SSIs)

Structural Measures: 4 measures

- Participation in a systematic clinical database registry for general surgery
- Participation in a systematic clinical database registry for nursing sensitive care
- Participation in a systematic clinical database registry for stroke care
- Participation in a systematic database for cardiac surgery

HCAHPS: 1 new measure

Transitions of care

5. Forms to facilitate the reporting process
    - Notice of Participation
    - Data Accuracy and Completeness
    - Request for Withholding Data From Public Reporting
    - Validation Appeal
    - Extraordinary Circumstances/ Disaster Waiver Request
    - Healthcare Associated Infection/ National Healthcare Safety Network Exception Request
    - Reconsideration Request (2 parts)

C.1. Need and Legal Basis for New Measures

Continued expansion of the quality measure set is consistent with the letter and spirit of both the DRA and the ACA. CMS' transition from a passive reporter of quality information to an active purchaser of care under VBP in particular raises the stakes for meaningful quality measurement in a manner that reflects the breadth of quality care delivered in the hospital. As reflected by the addition of 9 new claims-based measure sets, every effort has been made to reduce burden by using secondary data. However, these claims-based measures have the disadvantage of not representing patients across all population and payer groups, and also are limited in the depth of information available.

Below we describe the justification for the new measures and measure sets that are not claims-based. Each new measure is NQF-endorsed, thereby, meeting the requirement of section 1886(b)(3)(B)(viii)(IX) of the Social Security Act. In addition, each new chart abstracted measure is part of data already collected by the Joint Commission's (JCO) for the hospitals it accredits (approximately 85% of hospitals are accredited by JCO). Additional justifications for each measure set are provided below.

a. Chart-Abstracted Measure Sets and New Measures within Existing Measure Sets

Chart-abstracted measures assess care delivery more completely across the range of patient populations and at the level of depth needed to assess quality. The four new chart-abstracted measure sets (ED, IMM, STK, VTE) reflect important areas of care delivery.

The ED throughput measure set has two measures which provide insight into processes of care in the emergency department. Reducing the time patients remain in the ED can improve access to treatment and increase the quality of care, and capability of the hospital to provide adequate treatment to patients. ED overcrowding may result in delays in the administration of medication such as antibiotics for pneumonia and has been associated with perceptions of compromised emergency care. For patients with non-ST-segment elevation

myocardial infarction, long ED stays were associated with decreased use of guideline-recommended therapies and a higher risk of recurrent myocardial infarction. In addition, these measures also address ED overcrowding, which the IOM identified as a major quality issue, and which may be indicative of poor care coordination, communication, or efficiency of service provision beyond the walls of the emergency department. Overcrowding and heavy emergency resource demand have led to a number of problems, including ambulance refusals, prolonged patient waiting times, increased suffering for those who wait, rushed and unpleasant treatment environments, and potentially poor patient outcomes. Finally, when EDs are overwhelmed, their ability to respond to community emergencies and disasters may be compromised.

The global IMM measure set has two measures, one for influenza (flu) and one for pneumonia vaccination. Increasing flu and pneumonia vaccination could reduce unnecessary hospitalizations and secondary complications particularly among high risk populations such as the elderly. About 36,000 adults die annually and over 200,000 are hospitalized for flu-related causes. Older adults are more vulnerable, and adults over 65 comprise about 90 percent of deaths related to flu. Vaccinations can significantly reduce the number of flu related illnesses and deaths. There are also two immunization measures in the pneumonia measure set. The global measure set was added to acknowledge the importance of immunization to all hospital inpatients regardless of admission diagnosis.

The stroke measure set has 8 measures. Stroke is a topic of great relevance to the Medicare population due to its impact on morbidity and mortality, and it is an area with great potential for quality improvement for hospitals caring for stroke patients. Stroke is the third most common cause of death in the United States and is one of the top 20 conditions contributing to Medicare costs. Approximately 8 to 12 percent of ischemic strokes are fatal, and mortality following stroke is influenced by the quality of care provided to patients during their initial hospitalization. The processes of care captured by these measures are widely recognized as evidence-based approaches to minimize secondary strokes and other stroke complications. Together, they provide the hospital IQR program with a comprehensive view of how well stroke care is being managed in a hospital setting.

The VTE measure set has 6 measures. It is widely agreed that VTE is the number one preventable cause of hospital death in the United States and the cost of VTE when it occurs is very high. A recent study from AHRQ in Health Affairs highlighted that when an acute VTE event occurs, it increases the costs of care by 25 percent. VTE prevention with pharmacologic agents can impact the cost effectiveness of care. However, anticoagulation therapy poses risks to patients and often leads to adverse drug events due to complex dosing, requisite follow-up monitoring and inconsistent patient compliance. The use of standardized practices for anticoagulation therapy that includes patient/caregiver

involvement may reduce the risk of adverse drug events. These measures are aimed at preventing the incidence of potentially preventable VTE. The Hospital IQR Program already had 2 measures of VTE prophylaxis for surgical patients in the SCIP measure set, but these had a more narrow focus. We believe that the inclusion of the VTE measure set in the Hospital IQR Program provides a comprehensive view of how well VTE care is being managed in a hospital setting.

The PC measure set has 1 new measure, Elective delivery Prior to 39 Completed weeks gestation: Percentage of babies electively delivered prior to 39 completed weeks gestation. This measure was recommended for adoption by the Measure Applications Partnerhship to align with other quality reporting programs including Medicaid and JCO. Up to 10 percent of all deliveries are scheduled as induced or surgical deliveries before 39 weeks that are not medically indicated. It is estimated that medical care in the first year of life for preterm babies covered by the Medicaid program averages $20,000 compared to $2,100 for full-term infants. Medicaid pays for slightly less than half of the nation's births each year. Even a 10 percent reduction in deliveries occurring prior to 39 weeks would generate over $75 million in annual Medicaid savings.

The AMI measure set includes one new measure - AMI-Statin prescribed at Discharge. Current scientific evidence supports the continuation of statins for AMI patients. Several randomized clinical trials have proven the benefits of statin drugs (also known as HMG Co-A reductase inhibitors) in reducing the risk of death and recurrent cardiovascular events in a broad range of patients with established cardiovascular disease, including those with prior myocardial infarction. Current ACC/AHA guidelines place a strong emphasis on the initiation or maintenance of statin drugs for patients hospitalized with AMI, particularly those with LDL-cholesterol levels at or above 100 mg/dL. As a result of the strength of the evidence and guideline support, the ACC/AHA has developed a performance measure to assess this aspect of care for AMI patients. Because statins are generally well-tolerated, most AMI patients are appropriate candidates for this therapy. We believe that minimal additional burden will result from adoption of this measure into IQR program because the AMI population that is the focus of this measure is already part of the data collection effort; abstraction of very few additional data elements is needed to be abstracted for the new measure on this existing measurement population.

The SCIP measure set includes four new measures. SCIP is a national quality partnership of organizations committed to improving the safety of surgical care through the reduction of post-operative complications. The expansion of the SCIP measure set reflects the opportunities for improved outcomes and assurance of patient safety that present themselves through an ongoing focus on the quality of surgical care.

b. Other new measures and measure sets: infections, care transitions, and structural measures

CMS includes 5 healthcare associated infections (HAIs) in its measurement set for the 2015 APU determination. HAIs are among the leading causes of death in the United States. The CDC estimates that as many as 2 million infections are acquired each year in hospitals and result in approximately 90,000 deaths per year. It is estimated that more Americans die each year from HAIs than from auto accidents and homicides combined. HAIs not only put the patient at risk, but also increase the days of hospitalization required for patients and add considerable health care costs. HAIs are largely preventable through interventions such as better hygiene and advanced scientifically tested techniques for surgical patients. Therefore, many health care consumers and organizations are calling for public disclosure of HAIs, arguing that public reporting of HAI rates provides the information health care consumers need to choose the safest hospitals, and gives hospitals an incentive to improve infection control efforts. HHS has placed high priority on reducing HAIs,and adopted an action plan in January of 2009. More recently, the ACA required the inclusion of HAI measures in VBP. The 5 HAIs in our measure set align with the metrics in the HHS HAI Action Plan, and support VBP requirements. To minimize duplication of effort while fully integrating IQR data into quality improvement programs, HAI data for the IQR program are submitted through the National Healthcare Safety Network (NHSN). NHSN is a secure, Internet-based surveillance system maintained and managed by the CDC. NHSN enables healthcare facilities to collect and use data about HAIs, adherence to clinical practices known to prevent HAIs, the incidence or prevalence of multidrug-resistant organisms within their organizations, and other adverse events. HAI data collection for IQR has been approved through OMB No. 0920-0666.

Structural measures describe the environment in which providers care for patients. CMS includes 4 measures in its structural measures set, each describing participation in a different systematic clinical database registry. CMS defines a registry *as a collection of clinical data for purposes of assessing clinical performance, quality of care, and opportunities for quality improvement.* For each structural measure, the hospital must indicate on a web-based data collection form whether or not it participates in a systematic quality clinical database registry for that condition. CMS believes that participation in registries reflects a commitment to quality improvement. Many registries also collect outcome data and provide feedback to hospitals about their performance. Moreover, registries offer a potential future data source from which we can collect quality data. All 4 measures are NQF-endorsed but primarily for physicians. These 4 measures were selected anyway because they are registries in which hospitals commonly participate. CMS has the authority to adopt non-NQF measures from section 1886 (b)(3)(B)(IX)(bb) of the Social Security Act. Annual data submission for the structural measures occurs via Web-based

collection tool between April 1 and May 15 following the calendar year about which a hospital is queried.

HCAHPS, a standardized survey of hospital patients, is designed to assess the patient experience of care and is an ongoing part of the IQR program. The currently OMB approved version of the survey contains 27 items and covers eight key topics: communication with doctors, communication with nurses, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness of the hospital environment, and quietness of the hospital environment. HCAHPS data collection is approved through OMB No. 0938-0981. The proposed rule reflects the MAP recommendation to include three items related to the measurement of care transitions.

c. Forms used in the data collection process

In order to facilitate the Quality Data Reporting Program, several forms are necessary. These forms include: Notice of Participation; Data Accuracy and Completeness; Request for Withholding Data From Public Reporting; Quarterly Validation Appeal; Extraordinary Circumstances/ Disaster Waiver Request; Healthcare Associated Infection/ National Healthcare Safety Network Exception Request and the Reconsideration Request Form. Only the Data Accuracy and Completeness form must be completed by all IQR hospitals each year. The remainder are exceptions, exemptions, or one time only forms and hospitals may not need to complete any of these forms in any given year.

To begin participation in the Hospital IQR, all hospitals must complete a Notice of Participation. The Notice of Participation is completed online and explains the participation and reporting requirements for the program. Subsection D hospitals covered under Section 5001 (b) of the Deficit Reduction Act of 2005 must complete a Notice of Participation online. The form explains that in order to receive the full market basket update, the hospital is agreeing to allow CMS to publish their data for public viewing according to Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act. Hospitals not covered under Section 5001 (b) of the Deficit Reduction Act of 2005 may also wish to submit data and have their data published for public viewing. In order to accommodate those hospitals, and to allow hospitals covered under Section 5001 (b) to submit data on measures that may not be required under Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act a separate section of the online pledge form has been developed. This pledge portion gives CMS permission to collect and publish data that is voluntarily submitted by the hospital. These hospitals may choose to suppress a measure or measures prior to their posting on Hospital Compare. A form to request suppression of data is included in this package. This form can be located on QualityNet.org. In order to reduce burden, a hospital that indicated its intent to participate will be considered an active Hospital IQR participant until

CMS determines a need to pledge again or the hospital submits a withdrawal to CMS. Hospitals that no longer wish to participate in the Hospital IQR program or those who no longer wish to submit data for publishing on Hospital Compare can notify CMS of their decision via the same Pledge form discussed above.. This form can be found on the QualityNet website and can be mailed or faxed to their Quality Improvement Organization (QIO).

Annually, Subsection D hospitals covered under Section 5001 (b) of the Deficit Reduction Act of 2005 must complete a data accuracy and completeness acknowledgment form at the end of reporting year. This requirement was added based on a U.S. Government Accountability Office report from 2006 which recommended that CMS require hospitals to "formally attest to the completeness of the quality data that they submit quarterly". This form is a simply acknowledgement that the data a hospital has submitted is complete and accurate and is completed annually, online.

Hospitals that submit data not required by Sections 1886(b)(3)(B)(viii)(I) and (II) of the Social Security Act may elect to have that data withheld from public reporting by completing the Request for Withholding Data from Public Reporting form. This form is available on the Quality Net website. Once the form is submitted, data can be withheld for the quarter in which the form is submitted. However, the data will be released on *Hospital Compare* for subsequent releases unless the hospital submits a new Request for Withholding form indicating the measures the hospital would like to withhold from public reporting for the period.

CMS performs a random selection of Inpatient Prospective Payment Systems (IPPS) hospitals on an annual for validation. Validation rates are based on measure outcome matches. A hospital must have 75 percent or higher Overall Reliability Rate to pass the validation for the quarter. When the Overall Reliability Rate is less than 75 percent, the hospital may elect to appeal the validation results by submitting a quarterly validation appeal form to its Quality Improvement Organization (QIO). This form is found on Quality Net.

In the event of extraordinary circumstances not within the control of the hospital such as a natural disaster, a hospital can request a waiver or extension. For the hospital to receive consideration for an extension or waiver they must submit an Extraordinary Circumstances/Disaster Waiver Request Form. This form can be found online and can be completed online, by fax or by mail.

Hospitals that do treat the conditions or have treatment locations defined for the Healthcare Associated Infection/ National Healthcare Safety Network (NHSN) measures have the option to either complete the enrollment process with NHSN and indicate that they do not have patients that meet the measures requirements or they can submit an Exception Request. The exemption request

form will reduce the burden of completing the entire NHSN enrollment process for the hospitals that meet the exception requirement.

When a hospital does not meet the IQR Program requirements, the hospital may submit a request for reconsideration to CMS. When CMS determines that a hospital did not meet the Hospital Quality Reporting Program requirement(s), the hospital may submit a request for reconsideration to CMS, by the deadline identified on the Annual Payment Update Notification letter. This form can be found on the Quality Net website or online. This form will be accepted online beginning 1/1/13.

1. Information Users

CMS will use the information collected to set payment rates for value-based purchasing. Quality Improvement Organizations (QIOs) will use this information to identify opportunities for improvement, and to effectively target quality improvement initiatives in order to meet the statutory requirements for QIOs. The information will be made available to hospitals for their use in internal quality improvement initiatives. The information is used by CMS to direct its contractors to focus on particular areas of improvement, and to develop quality improvement initiatives. Most importantly, this information is available to beneficiaries, as well as to the public in general, to provide hospital information to assist them in making decisions about their health care. CMS conducts focus groups or market testing prior to public reporting hospital quality data on the Hospital Compare website.

2. Improved Information Technology

To assist hospitals in standardizing data collection initiatives across the industry, CMS maintains the CMS Abstraction and Reporting Tool (CART). CART is a free CMS-developed tool. CMS provides hospitals with training in CART. In addition, the Agency provides the secure data warehouse and use of the QualityNet (Qnet) Exchange website for storage and transmittal of the data as well as data validation and aggregation services prior to the release of data to the CMS website. The QualityNet website also provides a platform for submission of data on structural measures. Hospitals also have the option of using Joint Commission ORYX vendors to transmit the data. Attached are documents that describe each reporting tool. CMS has arranged for the QIOs to provide technical assistance to hospitals having difficulty with these tools. CMS will continue to improve these tools to make data submission easier for hospitals, as well as increase the utility of the data provided by the hospitals.

For the claims-based measures this section is not applicable, because all can be calculated based on data that are already reported to the Medicare program for

payment purposes. Therefore, no additional information technology will be required for hospitals for these measures.

a. Duplication of Similar Information

The information to be collected is not duplicative of similar information collected by the Centers for Medicare & Medicaid Services. In fact, the purpose of this effort is to reduce the reporting burden for the collection of quality of care information by allowing hospitals to submit electronic data in lieu of submitting paper charts, or to utilize electronic data that they currently report to JCO for accreditation. As required by statute, CMS maintains a set of quality measures which a hospital must report in order to receive the full annual payment update, and to qualify for payment incentives under VBP. Except as otherwise noted above, all measures are NQF-endorsed and aligned with JCO whenever possible. JCO-accredited hospitals already collect and submit data on all chart-abstracted measures in the expanded set.

Hospitals are required to complete and return a written form on which they agree to participate in the Hospital IQR program. This declaration, once signed, remains in effect – even as the set of measures expands or is modified -- until such time as a hospital specifically elects to revoke the pledge.

b. Small Business

Information collection requirements were designed to allow maximum flexibility specifically to small hospitals wishing to participate in hospital reporting. This effort will assist small hospitals in gathering information for their own quality improvement efforts.

c. Less Frequent Collection

We have designed the collection of quality of care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of hospital performance. This data is utilized to determine participation in the Inpatient Quality Reporting program as well as used as the basis for the Hospital Value Based Purchasing Program as mandated in the Affordable Care Act. Without this data we would not be able to administer either program.

7. Special Circumstances

Although participation is voluntary on the part of "subsection (d)" hospitals, all eligible hospitals must submit this data in order to receive the full market basket update for the given fiscal year.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice on May 11, 2012 (77 FR 27870).

CMS is supported in this initiative by JCO, NQF, MAP, CDC, and AHRQ. These organizations collaborate with CMS on an ongoing basis, providing technical assistance in developing and/or identifying quality measures, and assisting in making the information accessible, understandable, and relevant to the public.

d. Payment/Gift to Respondent

Under section 1886(b)(3)(B)(viii) of the Act, as modified by both the MMA and the DRA, hospitals are required to submit this data in order to receive the full market basket update and to qualify for additional VBP incentives under Section 1886(o). No other payments or gifts will be given to respondents for participation.

e. Confidentiality

All information collected under this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for Quality Improvement Organizations which can be found at 42 CFR Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication and are HIPAA compliant. The clinical warehouse also voluntarily meets or exceeds the HIPAA standards, please see the attached HIPAA compliance summary.

11. Sensitive Questions

Case Specific clinical data elements will be collected and are necessary to calculate statistical measures. These statistical measures are the basis of all subsequent improvement initiatives derived from this collection and cannot be calculated without the case specific data. This sensitive data will not, however, be released to the public. Only hospital specific data will be released to the public after consent has been received from the hospital for the release. The patient specific data remaining in the data warehouse after the data is aggregated for release for public reporting will continue to be subject to the strict confidentiality regulations in 42 CFR Part 480.

f. Burden Estimate (Total Hours & Wages)

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) sets out requirements for the Inpatient Quality Reporting program. Under section 1886(b)(3)(B)(viii)(V) of the Act, we were required to add other measures that reflect consensus among affected parties and, to the extent feasible and practicable, must include measures set forth by one or more national consensus building entities. In this proposed rule, we are setting out the measures that we propose to require for FY 2015. This burden estimate includes both newly added

measures and measure sets and those for which we are requesting renewal. It excludes burden associated with the NHSN and HCAHPS measures, both of which are submitted under separate OMB numbers.

We estimate the total burden as being approximately 6.30 million hours for 3,300 IPPS hospitals and an additional 0.46 million hours for another 1,100 non-IPPS hospitals, for a total of approximately 6.75 million hours.[1] The average reporting burden per hospital is smaller for non-IPPS hospitals than for IPPS hospitals. This is most likely because the non-IPPS hospitals submit measures voluntarily, and therefore may choose to do so for only a subset of the measure sets.

The total time required per hospital is highly variable. The time required per record measure set varies. The number of records per hospital per measure set depends on the bed size of the hospital, and the patient case mix. Moreover, the distribution of hospital bed sizes varies by measure set. Therefore, the following assumptions were made to compute these estimates. Mean number of records per measure set were obtained directly from the IQR program for the AMI, HF, PN, and SCIP measure sets using data from the 3rd quarter in 2010 through the 2nd quarter in 2011. Mean abstraction times for these measure sets were also estimated from the IQR program, with the mean times reported by our Clinical Data Abstraction Contractor (CDAC) rounded to the nearest 5 minutes, and used for all hospitals. For VTE and STK, we estimated mean abstraction times using information provided by CDAC for AMI, HF, PN, and SCIP, factoring in the number of measures per measure set and the relative severity of the cases. To estimate the total number of records per hospital for VTE and STK, we combined information on expected number of discharges per hospital bed size in 5 categories (< 100 beds, 100-199 beds, 200-299 beds, 300-499 beds, and 500 beds), with minimum sampling requirements for hospitals with different expected population counts. Minimum sampling requirements were obtained from QualityNet.[2] Annual numbers of discharges in each measure set and bed size category were estimated from the 2007-2009 National Hospital Discharge Survey (NHDS) public use files.[3] These estimates were divided by the total number of hospitals in each bed size category derived from the American Hospital Association (AHA) 2010 survey. We are aware that many of

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[1] The sum of the IPPS and non-IPPS components do not equal the total because of rounding.

[2] Specifications Manual, Version 4.1, Discharges 07/01/2012 to 12/31/2012, http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier4&cid=1228771525863, last accessed 4/3/2012.

[3] National Hospital Discharge Survey public use files, 2007-2009, http://www.cdc.gov/nchs/nhds/nhds_questionnaires.htm#public_use, last accessed, October 27, 2011.

Measure Set	Estimated time per record (minutes)	Number reporting periods/ year	ber of hospitals reporting	Average number records (range)/ hospital/ period	Annual burden (hours)
CHART ABSTRACTION					
IPPS Hospitals (3,300)					
Acute myocardial infarction (AMI)	30	4	3,300	41 (0- 78)	270,000
Heart failure (HF)	20	4	3,300	63 (0- 76)	280,000
Pneumonia (PN)	35	4	3,300	76 (0- 60)	590,000
Surgical care improvement project (SCIP)	55	4	3,300	120 (0-392)	1,450,000
Emergency department (ED) throughput/Immunizations (IMM)	15	4	3,300	295 (0-306)	970,000
Stroke (STK)	50	4	3,300	32 (0- 45)	350,000
Venous thromboembolism (VTE)	40	4	3,300	247 (0-360)	2,170,000
Perinatal care (PC)	10	4	3,300	76 (0-145)	170,000
Non-IPPS Hospitals (1,100)					
Acute myocardial infarction (AMI)	30	4	1,100	5 (0-78)	10,000
Heart failure (HF)	20	4	1,100	6 (0-76)	10,000
Pneumonia (PN)	35	4	1,100	21 (0-60)	50,000
Surgical care improvement project (SCIP)	55	4	1,100	17 (0-392)	70,000
Emergency department (ED) throughput/Immunizations (IMM)	15	4	1,100	27 (0-306)	30,000
Stroke (STK)	50	4	1,100	3 (0-45)	10,000
Venous thromboembolism (VTE)	40	4	1,100	82 (0-360)	240,000
Perinatal care (PC)	10	4	1,100	21 (0-145)	20,000
Subtotal chart-based					6,690,000
OTHER ACTIVITIES					
All Hospitals (3,300 IPPS + 1,100 non-IPPS)					
Population and sampling and set-up for 3 new measure sets (first quarter)	60	1	4,400	3	10,000
Population and sampling for 3 new measure sets (remaining 3 quarters)	15	3	4,400	3	10,000
Population and sampling for 5 ongoing measure sets	15	4	4,400	5	20,000
All other forms and structural measures	15	1	4,400	1	0
Review reports for claims-based measure sets	60	4	4,400	1	20000
Subtotal other activities					60,000
Total					**6,750,000**

these estimates may have been made with error including: sampling error associated with the NHDS; lack of alignment in bed size distributions between the NHDS, AHA, and the IQR program; and voluntary reporting of more than the minimum sample size for IQR. However, we believe these errors to be relatively small as we were able to directly compare our approach for estimating the number of records abstracted for AMI, HF, and PN data using NHDS/AHA data with the gold standard of direct measurement from program data. The survey data derived estimates were 8% lower for PN than program data, and 5% (HF) and 12% (AMI) higher than program data.

For PC, we lacked details regarding bed size distributions because the NHDS does not contain data on gestational age at birth. We obtained the total number of births at 37-38 weeks in 2009 from the National Vital Statistics System.[4] We obtained the distribution of
deliveries by bed size from the 2007-2009 NHDS. Because the annual number of pneumonia (PN) discharges and deliveries at 37-38 weeks were similar, we used the same estimates for the average number of records abstracted per hospital for PC as for PN. This is likely to over-estimate the number of records for PC, because a higher proportion of PN cases are treated at hospitals with a bed size less than 100 than deliveries. In these small hospitals, a larger sampling fraction is needed. This means that the average number needed of PC records per hospital should be somewhat smaller than that needed for PN.

Time estimates for activities other than abstracting charts, including completion of forms for structural measures, routine reporting of population and sampling numbers for ongoing measures, and set up and reporting of population and sampling for new measures, and review of records were made in consultation with our Hospital IQR Support Contractor which is responsible for routine interface with hospitals and Quality Improvement Organizations regarding the IQR program.

To acknowledge that all estimates are approximate, the average numbers of records per hospital per reporting period were rounded to the nearest whole number. The annual hourly burden estimates per measure set or other activity were rounded to the nearest 10,000 hours.

We anticipate that the approximately 6.75 million hours of work will be completed by Medical Records and Health Information Technicians. In May 2011, the mean hourly wage for this job title in general medical and surgical hospitals was $18.25.[5] Therefore, we estimate the total annual burden would be about $123 million. A substantial fraction of the 6.75 million hours of time

[4] "Table 23. Births, by birthweight and gestational age and by race and Hispanic origin of mother: United States, 2009", in Martin JA, Hamilton BE, Ventura SJ, et al. Births: Final data for 2009. National vital statistics reports; vol 60 no 1. Hyattsville, MD: National Center for Health Statistics. 2011, p. 57. http://www.cdc.gov/nchs/data/nvsr/nvsr60/nvsr60_01.pdf, last accessed April 3, 2012.

support other hospital reporting activities, for example, those associated with accreditation by JCO or the American Osteopathic Association (AOA). For example, for the FY 2012 APU, 90% of the chart abstracted measures for AMI, PN, HF, and SCIP were submitted by JCO accredited hospitals, and an additional 2% of records were submitted by AOA accredited hospitals. Therefore, in 2012, we estimate that about 2.5 million hours of chart-abstraction on IQR also served to support private sector accreditation programs. As all new chart-based measures are fully aligned with JCO, we anticipate that as the number of measure sets reported to IQR expands, so will the number of measure sets reported to JCO.

g. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

h. Cost to Federal Government

The cost to the Federal Government includes costs associated with the collection and validation of the data. These costs are estimated at $2,550,000.00 annually for the validation, and quality reporting contracts. Additionally, this program takes 3 CMS staff at a GS-13 level to operate. GS-13 approximate annually salary is $92,001 for an additional cost of $276,000. Hospitals will be reporting data either through the Joint Commission or directly to CMS through CART or QualityNet exchange. This tool has already been developed and updated for use in the QIO program.

For the claims-based measures, the cost to the Federal Government is minimal. CMS plans to use data from the Medicare warehouse (claims data) that is already being collected for index hospitalizations to calculate the mortality rates, therefore, no additional data will need to be submitted by hospitals.

i. Program or Burden Changes

As shown above, this program has significantly increased the number of measures included in its data collection requirements. These increases support adherence to: Section 1886(b)(3)(B)(viii) of the SSA, which required the expansion of the IQR program between FY 2008-2012; Section 3013 of ACA which modified Section 931 of the Public Health Service Act by requiring CMS "identify, not less often than triennially, gaps where no quality measures exist and existing quality measures that need improvement, updating or expansion"; and Section 1886(o) of the SSA which requires CMS to use data reported through the IQR for its VBP program.

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[5]"29-2071. Medical Records and Health Information Technicians, Occupational Employment and Wages, May 2011." Bureau of Labor Statistics, Occupational Employment Statistics. http://www.bls.gov/oes/current/oes292071.htm#nat, last accessed April 3, 2012.

CMS program reduces the reporting burden for quality of care information collected by allowing hospitals to abstract data directly into electronic systems in lieu of submitting paper charts, or to utilize electronic data that they already report to JCO for accreditation. The long-term vision for the IQR program is to allow hospitals to submit data directly from their electronic health records, which we anticipate will reduce burden substantially. The 2012 Electronic Reporting Pilot (76 FR 74490) is an important step in the transition from paper to electronic reporting.

j. Publication/Tabulation Date

The goal of the data collection is to tabulate and publish hospital specific data. We will continue to display quality information for public viewing as required by the SSA under Section 1886(o)(10). IQR data from this initiative is currently used to populate the Hospital Compare Web site, www.hospitalcompare.hhs.gov. Hospital quality data on Hospital Compare is updated on a quarterly basis.

k. Expiration Date

We request an exemption from displaying the expiration date because these tools will be used on a continuous basis by hospitals reporting quality data.