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

A. <u>Background</u>

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) consumer data from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey; and (d) 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 "consensusbased 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 2014 IPPS proposed rule. The proposed rule also includes some measures and measure sets that were finalized for adoption for the 2016 APU determination in previous years. 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 2016 APU determination will be based on IQR data reported and supporting forms submitted by hospitals between January 2014 and December 2014. The FY 2014 IPPS proposed rule recommends the collection of 56 measures to be used for the FY 2016 APU. It recommends retirement of an additional 8 measures and adopt 5 new claims based measures. 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 forms to support the general reporting process are described in section 4.

2. New Measure Sets

No new chart-abstracted measures or measure sets are being proposed for FY 2016.

New measure sets derived through secondary data analysis of administrative data

- 30-day risk standardized Stroke mortality (not endorsed, MAP does not support inclusion but consumers and purchasers voiced support given importance of stroke outcomes)
- 30-day risk standardized Stroke readmission (not endorsed, MAP does not support inclusion but consumers and purchasers voiced support given importance of stroke outcomes)
- 30-day risk standardized COPD mortality (NQF #1893, MAP supports inclusion)
- 30-day risk standardized COPD readmission (not endorsed, MAP supports inclusion)
- AMI Cost per Episode of care (not endorsed, MAP supports direction of this measure)

3. Measures Proposed for Removal

- PN 3b: Blood cultures performed in the ED prior to receipt of initial antibiotic
- HF1: Discharge instructions
- IMM 1: Pneumococcal Immunization
- Participation in a systematic database registry for Stroke Care
- AMI–2: Aspirin Prescribed at Discharge
- AMI–10: Statin Prescribed at Discharge
- HF–3: ACEI or ARB for LVSD
- SCIP-Inf–10: Surgery Patients with Perioperative Temperature Management

4. Forms to facilitate the reporting process

- Notice of Participation
- Data Accuracy and Completeness
- Request for Withholding Data From Public Reporting

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- Extraordinary Circumstances/ Disaster Waiver Request
- Healthcare Associated Infection/ National Healthcare Safety Network Exception Request
- Reconsideration Request (2 parts)
- HVBP Review and Correction Form
- HVBP Appeals Form

5. Forms to facilitate the validation process

- Validation Template for Central Line Associated Bloodstream Infection (CLABSI)
- Validation Template for Catheter-Associated Urinary Tract Infection (CAUTI)
- Validation Template for MRSA Bacteremia (MRSA).
- Validation Template for Clostridium Difficile (CDI).

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 5 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.

a. 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 templates used for validation are only utilized by approximately 600 hospitals annually that are chosen, mostly at random, for validation. 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. In support of the Fiscal Year (FY) 2014 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule, we propose a requirement for validation reporting healthcare associated infection (HAI) events as part of the Inpatient Quality Reporting program for the FY 2016 payment determination and future years. Each hospital selected for validation is to produce a list of patients/lab results associated with the particular HAI being validated. This process includes validation templates for CLABSI, CAUTI, MRSA and CDI. We proposed to divide the up to 600 hospitals selected for validation into two halves; approximately 300 would need to produce the CLABSI and CAUTI templates and the other 300 hospitals would need to only produce the MRSA and CDI templates.

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.

Hospitals may appeal the calculation of their performance assessment with respect to the performance standards, as well as their Total Performance Score (TPS). Hospitals may submit an appeal using the HVBP Appeals Form within 30 calendar days of the date of the CMS receipt of CMS' review and corrections decision letter.

Hospitals may review and request recalculation of their hospital's performance scores on each condition, domain, and Total Performance Score (TPS) using the HVBP Review and Correction Form within 30 calendar days of the posting date of the Value-Based Percentage Payment Summary Report on QualityNet.

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. <u>Improved Information Technology</u>

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 claims-based measures 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. <u>Duplication of Similar Information</u>

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. <u>Less Frequent Collection</u>

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.

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 is anticipated to be published on August 1, 2012. The FY 2013 IPPS Proposed Rule can be found on the CMS website at http://www.cms.hhs.gov/AcuteInpatientPPS/IPPS/list.asp. Comments are currently being submitted on this notice, and CMS will respond to those comments accordingly.

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. <u>Confidentiality</u>

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 5.9 million hours for 3,300 IPPS hospitals and an additional 0.4 million hours for another 1,100 non-IPPS hospitals, for a total of approximately 6.3 million hours. The average reporting

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

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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² <u>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.</u>

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.

				Average	
				number	
	Estimated	Number		records	
	time per	reporting	ber of	(range)/	Annual
	record	periods/	hospitals	hospital/	burden
Measure Set	(minutes)	year	reporting	period	(hours)
CHART ABSTRACTION					
(PPS Hospitals (3,300)	0.5	4	2.200	41 (0. 70)	00/ 00/
Acute myocardial infarction (AMI)	25	4	3,300	41 (0- 78)	226,000
Heart failure (HF)	15	4	3,300	63 (0- 76)	208,000
Pneumonia (PN)	35	4	3,300	76 (0- 60)	585,000
Surgical care improvement project (SCIP)	50	4	3,300	120 (0-392)	1,320,000
Emergency department (ED)	12	4	2 200	205 (0.206)	770.00
throughput/Immunizations (IMM)		4	3,300	295 (0-306)	779,000
Stroke (STK)	50	4	3,300	32 (0- 45)	352,000
Venous thromboembolism (VTE)	40	4	3,300	247 (0-360)	2,174,000
	10	4	3,300	76 (0-145)	167,000
Perinatal care (PC) Non-IPPS Hospitals (1,100) Acute myocardial infarction (AMI)	25	4	1,100	5 (0-78)	4,000

Heart failure (HF)	15	4	1,100	6 (0-76)	2,000
Pneumonia (PN)	35	4	1,100	21 (0-60)	18,000
Surgical care improvement project (SCIP)	50	4	1,100	17 (0-392)	22,000
Emergency department (ED)					
throughput/Immunizations (IMM)	15	4	1,100	27 (0-306)	10,000
Stroke (STK)	50	4	1,100	3 (0-45)	11,000
Venous thromboembolism (VTE)	40	4	1,100	82 (0-360)	79,000
Perinatal care (PC)	10	<u>4</u>	<u>1,100</u>	21 (0-145)	5,000
Subtotal chart-based					5,962,000
OTHER ACTIVITIES All Hospitals (3,300 IPPS + 1,100 non-IPPS)					
Population and sampling for 8 ongoing measure sets	15	4	4,400	8	35,000
Review reports for claims-based measure sets	60	4	4,400	1	20,000
HAI Validation Templates (CLABSI, CAUTI)	1,200	3	300	1	18,000
HAI Validation Templates (MRSA, CDI)	960	3	300	1	14,000
All other forms and structural measures	15	1	4,400	1	1,000
Subtotal other activities					88,000
<u>Total</u>					<u>6,050,000</u>

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 submitted 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 required. This means that the average number required of PC records per hospital should be somewhat smaller than that required 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 6.05 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

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.

hospitals was \$18.25.⁵ Therefore, we estimate the total annual burden would be about \$123 million. A substantial fraction of the 6.05 million hours of time 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. <u>Capital Costs (Maintenance of Capital Costs)</u> 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 \$9,550,000.00 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. <u>Program or Burden Changes</u>

As shown above, this program has increased the number of measures included in its data collection requirements however, since the proposed measures to be added are claims based and several chart abstracted measures are proposed for removal, we estimate a reduction in burden associated with data collection for chart abstracted measures and associated forms. 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

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.

"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.

Additionally CMS proposes to reduce the reporting burden for quality of care information collected by allowing hospitals to abstract some 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. <u>Publication/Tabulation Date</u>

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.