

Supporting Statement – Part A
Quality Measures and Procedures for Hospital Reporting of Quality Data for the FY
2018 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 ACA modified Section 931 of the Public Health Service Act by requiring that 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 health care 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.

1. New IQR Quality Measure Sets and Measures

a. Introduction

The 2018 APU determination will be based on IQR data reported and supporting forms submitted by hospitals between January 2016 and December 2016. 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.

b. New Measures

The following measures are being proposed for FY 2018: (1) Hospital Survey on Patient Safety Culture (structural); (2) Kidney/UTI Clinical Episode-Based Payment Measure (claims-based); (3) Cellulitis Clinical Episode-Based Payment Measure (claims-based); (4) Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure (claims-based); (5) Lumbar Spine Fusion/Re-Fusion Clinical Episode-Based Payment Measure (claims-based); (6) Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA/TKA (claims-based); (7) Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (claims-based); and (8) Excess Days in Acute Care after Hospitalization for Heart Failure (claims-based).

c. Measures Proposed for Removal

The following measures are being proposed for removal: (1) STK-01 Venous Thromboembolism Prophylaxis (NQF #0434); (2) STK-06: Discharged on Statin Medication (NQF #0439); (3) STK-08: Stroke Education (NQF endorsement removed); (4) VTE-1: Venous Thromboembolism Prophylaxis (NQF #0371); (5) VTE-2: Intensive Care Unit Venous Thromboembolism Prophylaxis (NQF #0372); (6) VTE-3: Venous Thromboembolism Patients with Anticoagulation Overlap Therapy (NQF #0373); and (7) AMI-7a Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival (NQF #0164); (8) IMM-1 Pneumococcal Immunization (NQF #1653); and (9) SCIP-Inf-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).

d. 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 Acknowledgement
- Request for Withholding Data from Public Reporting
- Measure Exception Form
- Reconsideration Request Form

- HVBP Review and Corrections Form
- HVBP Appeals Form
- Extraordinary Circumstances Extensions/Exemptions Request Form
- IQR Validation Review for Reconsideration Request
- Validation forms for CLABSI, CAUTI, MRSA, and CDI measures

Only the Data Accuracy and Completeness Acknowledgment form must be completed by all IQR hospitals each year. The remainder is exceptions, exemptions, or one time only forms, and hospitals may not need to complete any of these forms in any given year.

The validation forms for CLABSI, CAUTI, MRSA, and CDI measures are being revised with this PRA package with updated dates. Two additional information collection forms listed above are being revised with this PRA package: (1) Measure Exception Form and (2) Extraordinary Circumstances Extensions/Exemptions Request Form.

The Measure Exception Form is being updated to allow for exceptions to reporting Perinatal Care (PC) and Emergency Department (ED) measures, in addition to Healthcare-Associated Infection (HAI) measures and to add the Hospital Value-Based Purchasing and Hospital-Acquired Condition (HAC) Reduction Programs. The Extraordinary Circumstances Extensions/Exemptions Request Form is being updated so that it may now be used across the following programs: Hospital Inpatient Quality Reporting (IQR), Inpatient Psychiatric Facility Quality Reporting (IPFQR), PPS-Exempt Cancer Hospital Quality Reporting (PCHQR), HVBP, HAC Reduction, Hospital Readmissions Reduction Program, Hospital Outpatient Quality Reporting (OQR), and Ambulatory Surgical Center Quality Reporting (ASCQR).

B. Justification

1. Need and Legal Basis

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 seven new claims-based measures, every effort has been made to reduce burden by using secondary data. However, 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.

To begin participation in the Hospital IQR, all hospitals must complete a Notice of Participation. The Notice of Participation 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. The form explains that in order to receive the full market basket update, the hospitals are 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 pledge form has been developed. This pledge portion gives CMS permission to collect and publish data that are voluntarily submitted by a hospital. These hospitals may choose to suppress a measure or measures prior to their posting on *Hospital Compare*. 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 that no longer wish to submit data for publishing on *Hospital Compare* can notify CMS of their decision via the same Pledge form discussed above.

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 each reporting year. This requirement was added based on a U.S. Government Accountability Office report from 2006 that recommended that CMS require hospitals to “formally attest to the completeness of the quality data that they submit.” This form is simply an acknowledgement that the data a hospital has submitted is complete and accurate and is completed annually.

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 those data withheld from public reporting by completing the Request for Withholding Data from Public Reporting form. 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 basis for validation. 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 finalized our proposal 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.

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 who meet the measures requirements or they can submit an Exception Request. The Exception Request Form will reduce the burden of completing the entire NHSN enrollment process for the hospitals that meet the exception requirement.

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 online. This form was enabled online beginning January 1, 2013.

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

All of the above mentioned forms have been submitted previously under OMB control number 0938-1022.

2. Information Users

CMS will use the information collected to set payment rates for value-based purchasing. 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, to provide hospital information to assist them in making decisions about their health care. CMS conducts focus groups or market testing prior to publicly reporting hospital quality data on the *Hospital Compare* website.

3. Use of Information Technology

To assist hospitals in standardizing data collection initiatives across the industry, CMS continues to improve data collection tools in order 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.

4. 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 The Joint Commission 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 aligned with The Joint Commission whenever possible. Joint-

Commission-accredited hospitals already collect and submit data on all chart-abstracted measures in the expanded set.

5. 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.

6. Less Frequent Collection

We have designed the collection of quality measure data to be the minimum necessary for data validation and calculation of summary figures to be used as reliable estimates of hospital performance.

7. Special Circumstances

Although participation is voluntary on the part of “subsection (d)” hospitals, all eligible hospitals must submit these 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, 2015. The FY 2016 IPPS Proposed Rule will also be published to the *Federal Register*. 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.

9. 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 these 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.

10. 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.

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. These 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 are aggregated for release for public reporting will continue to be subject to the strict confidentiality regulations in 42 CFR Part 480.

12. 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 2018. This burden estimate includes newly added measures, measure sets for which we are requesting renewal, as well as other activities resulting in hospital burden. It excludes burden associated with the NHSN and HCAHPS measures, which are submitted under separate OMB numbers.

We estimate the total burden as being approximately 7.6 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 8 million hours. 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 assumptions used to compute these estimates are described here. All abstraction time estimates for the global (ED/IMM) population sets came directly from our Clinical Data Abstraction Contractor (CDAC) experience. Numbers of cases per topic area for these measure sets and stroke and VTE, were extrapolated from data submitted to the clinical data warehouse between the 3rd quarter in 2013 and the 2nd quarter in 2014. Volume estimates for the perinatal care and sepsis measures were estimated from data on the number of expected claims per hospital from the National Hospital Discharge Survey 2010. Abstraction time estimates per record for perinatal care and sepsis were assessed based on complexity and similarity with other measure sets. The mean times reported by our CDAC are rounded to the nearest five minutes and used for all hospitals.

The total time required per hospital is highly variable. The time required per record measure set also 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.

Measure Set	Estimated time per record (minutes)	Number reporting quarters per year	Number of hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) across hospitals
CHART ABSTRACTION					
IPPS Hospitals (3,300)					
Heart failure (HF)	15	4	3,300	59	194,205
Pneumonia (PN)	35	4	3,300	71	544,159
Surgical care improvement project (SCIP)	50	4	3,300	110	1,213,300
Emergency department (ED) throughput/ Immunizations (IMM)	35	4	3,300	260	1,998,843
Stroke (STK)	35	4	3,300	39	303,534
Venous thromboembolism (VTE)	40	4	3,300	198	1,742,840
Sepsis Measures	60	4	3,300	100	1,320,000
Perinatal care (PC)	10	4	3,300	76	167,200
Subtotal IPPS chart-based					7,484,081
Non-IPPS Hospitals (1,100)					
Subtotal Non-IPPS chart-based					- - - 373,380
Subtotal IPPS and Non-IPPS chart-based					7,857,461
OTHER ACTIVITIES					
All Hospitals (3,300 IPPS + 1,100 non-IPPS)					
Population and sampling for 8 ongoing measure	15	4	4,400	8	35,000

sets					
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
Reporting 16 electronic Clinical Quality Measures	160	2	4400	NA	23,467
All other forms and structural measures	15	1	4,400	1	1,000
Subtotal other activities					111,467
Total					7,968,928

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.

An Extraordinary Circumstances Extensions/Exemptions Request Form, which will be used across eight quality reporting programs (listed above) is also included within this PRA package. The burden associated with this form is expected to be negligible, as it will not be filled out by hospitals on a regular basis. This form is intended to be submitted by participants only in the event of an extraordinary circumstance or disaster. We believe that aligning this form across eight quality reporting programs will reduce burden to participants by allowing hospitals to apply for an extension for all applicable quality reporting programs at the same time.

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 100 hours.

We anticipate that the approximately 8 million hours of labor will be completed by Medical Records and Health Information Technicians. The labor performed can be accomplished by these staff with a mean hourly wage in general medical and surgical hospitals of \$16.42 per hour.¹ Per OMB's Circular A-76, in calculating direct labor, agencies should not only include salaries and wages, but also "other entitlements" such as fringe benefits.² This Circular provides that the civilian position full fringe benefit cost factor is 36.25 percent. Therefore,

¹ <http://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>

² http://www.whitehouse.gov/omb/circulars_a076_a76_incl_tech_correction

using these assumptions, we estimate an hourly labor cost of \$22.37 (\$16.42 base salary + \$5.95 fringe). Accordingly, we estimate the total annual burden would be about \$178 million.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. 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 \$10,050,000 annually for the validation and quality reporting contracts. Additionally, this program takes three CMS staff at a GS-13 level to operate. GS-13 approximate annual salary is \$92,000 for an additional cost of \$276,000.

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 are already being collected for index hospitalizations to calculate the mortality rates; therefore, no additional data will need to be submitted by hospitals.

15. Program or Burden Changes

As shown above, this program has increased the number of measures included in its data collection requirements. The added measures 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 to “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 collection in the long term by requiring hospitals to abstract some data directly into electronic systems in lieu of reviewing 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 encourage 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.

16. Publication/Tabulation Data

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 are currently used to populate the *Hospital Compare* website, www.hospitalcompare.hhs.gov. Hospital quality data on *Hospital Compare* are updated on a quarterly basis.

17. 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.

18. Certification Statement

We are not claiming any exceptions to the Certification for Paperwork Reduction Act Submissions Statement.