Supporting Statement – Part A
Additional Quality Measures and Procedures for Hospital Reporting of Quality Data for the FY 2009 IPPS Annual Payment Update (Surgical Care Improvement Project & Mortality Measures)

A. Background

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) sets out new requirements for the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. The IPPS RHQDAPU program was established to implement section 501(b) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173). It builds on our ongoing voluntary Hospital Quality Initiative which is intended to empower consumers with quality of care information to make more informed decisions about their health care while also encouraging hospitals and clinicians to improve the quality of care.

Section 5001(a) of Pub. L. 109-171 revises the mechanism used to update the standardized amount for payment for hospital inpatient operating costs. New sections 1886(b)(3)(B)(viii)(I) and (II) of the Act provide that the payment update for FY 2007 and each subsequent fiscal year will be reduced by 2.0 percentage points 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. Under sections 1886(b)(3)(B)(viii)(III) and (IV) of the Act, we must expand the "starter set" of quality measures that we have used since FY 2005, and to begin to adopt the baseline set of performance measures as set forth in a 2005 report issued by the Institute of Medicine of the National Academy of Sciences (IOM) under section 238(b) of the MMA, effective for payments beginning with FY 2007. The 2005 IOM report's "baseline" quality measures include Hospital Quality Alliance (HQA)-approved clinical quality measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS®) patient perspective survey, and three structural measures. The structural measures are: (1) implementation of computerized provider order entry for prescriptions, (2) staffing of intensive care units with intensivists, and (3) evidence-based hospital referrals. These measures originate from the Leapfrog Group's original "three leaps," and are part of the NQF's 30 safe practices.

In 2002, the Secretary of HHS entered into a collaboration with a hospital-industry led group established to promote voluntary hospital quality improvement and public reporting of hospital quality information. This collaboration is known as the Hospital Quality Alliance (HQA). The collaborators include the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, the Joint Commission on Accreditation of Healthcare Organizations (the Joint Commission), the National Quality Forum (NQF), the American Medical Association, the Consumer-Purchaser Disclosure Project, the American Association of Retired Persons, the American Federation of Labor Congress of Industrial Organizations, the Agency for Healthcare Research and Quality, as well as CMS. Over time, other organizations have joined this collaboration.

In the FY 2007 IPPS proposed rule, we proposed to increase the set of quality measures on which hospitals needed to report for the full annual update by adding 11 HQA-approved measures for purposes of the FY 2007 update (71 FR 24093). In the final rule, modified this

requirement, so that hospitals must pledge by August 15, 2006, to report quality data on the expanded set of 21 measures beginning with discharges that occur in the third calendar quarter of 2006 (July through September discharges).

Under section 1886(b)(3)(B)(viii)(V) of the Act, for payments beginning with FY 2008, we are 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.

Commenters on the FY 2007 IPPS proposed rule requested that we notify the public as far in advance as possible of any proposed expansions of the measure set and program procedures to encourage broad collaboration and to give hospitals time to prepare for any anticipated changes. Other commenters requested that we adopt additional quality measures and that we do as soon as feasible. For example, several commenters urged that we adopt the HCAHPS® patient survey as a part of the IPPS RHQDAPU program, while others suggested that we adopt more of the IOM measures as well as more outcome measures, including mortality measures that were not included in the 2005 IOM report's "baseline" quality measures. In response to these comments and as part of our continuing efforts to strengthen the IPPS RHQDAPU program, we are seeking comments on this proposal to expand the measurement set for FY 2008, beyond those measures that we adopted for purposes of the FY 2007 update. This expanded set would further broaden the scope of the IPPS RHQDAPU program by including the HCAHPS® patients' perspectives of care measures as well as surgical care and mortality outcome measures.

B. Adopted Quality Measures for FY 2008

1. Introduction

For FY 2008, we propose to add the following categories to the measure set:

. HCAHPS® Survey

HCAHPS® is also known as Hospital CAHPS or the CAHPS Hospital Survey.

The HCAHPS® survey is composed of the following 27 questions:

+ 18 substantive questions that measure critical aspects of the hospital experience (communication with doctors; communication with nurses; responsiveness of hospital staff; cleanliness and quietness of hospital environment; pain management; communication about medicines; and discharge information).
+ 4 questions that direct patients to complete only those survey questions that apply to them.
+ 3 questions to be used to adjust the mix of patients across hospitals.
+ 2 questions that support Congressionally-mandated reports, the "National Healthcare Disparities Report," and the "National Healthcare Quality Report."

. Surgical Care Improvement Project (SCIP)

+ SCIP-VTE 1: Venous thromboembolism prophylaxis ordered for surgery patient
+ SCIP-VTE 2: VTE prophylaxis received within 24 hours pre/post surgery
+ SCIP Infection 2: Prophylactic antibiotic selection for surgical patients

. Mortality

+ AMI 30-day mortality –- Medicare patients
+ HF 30-day mortality – Medicare patients

+ Pneumonia 30-day mortality – Medicare patients
Note: In the final CY 2007 OPPS rule, we withdrew the pneumonia 30-day mortality measure for purposes of the FY 2008 IPPS payment determinations, since the measure had not received NQF endorsement prior to publication of the final rule.

Request for Modification
Continued expansion of the quality measure set is consistent with the letter and spirit of the DRA. Section 1886(b)(3)(B)(viii)(III), as added by the DRA, requires the Secretary to expand the set of measures determined to be appropriate for the measurement of the quality of care furnished by hospitals in inpatient settings, beginning in FY 2008. In the FY 2008 IPPS proposed rule, we announced our intent to move quickly to add to the quality measures set for FY 2009 annual payment update determination (RHQDAPU). In support of this proposal, we request modification to this existing PRA package (number) in order to include additional measures within both the SCIP and mortality topics.

For FY 2009, the set of measures for the RHQDAPU program will consist of measures previously approved through the PRA process, as well as additional measures identified through this rulemaking. For FY 2009 the measurement set will therefore include the 27 quality indicators which were identified for FY 2008 and the following additional measures:

- Pneumonia 30-day Mortality (Medicare patients)
- SCIP Infection 4: Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose
- SCIP Infection 6: Surgery Patients with Appropriate Hair Removal

All of these measures have been approved by the Hospital Quality Alliance (HQA) for inclusion in the national voluntary hospital reporting set, and are fully specified and included in the joint CMS-The Joint Commission *Specifications Manual for National Hospital Quality Measures*. The measures offer important additions to our understanding of patient outcomes (mortality) and patient safety efforts, and could help encourage additional systems change in hospitals in the areas of pneumonia care and surgical services.

These three measures were recently endorsed by the National Quality Forum (NQF) and will be added to the set. CMS will propose that data collection for these measures for purposes of RHQDAPU (where needed) would begin in CY 2008.

Additionally, CMS plans to add one measure currently under endorsement review by the NQF. CMS plans to announce the addition of these measures, contingent on their receiving NQF endorsement, in the of the Calendar Year 2008 Outpatient Prospective Payment System final rule publication. This measure is the following:

- SCIP Cardiac 2: Surgery Patients on a Beta-Blocker Prior to Arrival Who Received a Beta-Blocker During the Perioperative Period

Contingent on NQF endorsement, CMS plans to propose that data collection for this measure for purposes of RHQDAPU (where needed) would begin in CY 2008.

B. Justification

1. Need and Legal Basis

The Surgical Care Improvement Project (SCIP) is a national quality partnership of organizations committed to improving the safety of surgical care through the reduction of post-operative complications. The primary goal of the partnership is to save lives by reducing the incidence of surgical complications by 25 percent by the year 2010. Partners in SCIP believe that a meaningful reduction in complications requires a systems approach to our challenges, which means that surgeons, anesthesiologists, primary care physicians and internal medicine specialists, perioperative nurses, pharmacists, infection control professionals, and hospital executives must work together to make surgical care improvement a priority. SCIP partners coordinate their efforts through a steering committee that includes representatives of the American Hospital Association, the American College of Surgeons, the American Society of Anesthesiologists, the Association of Perioperative Registered Nurses, the Joint Commission, the Institute of Healthcare Improvement, the Department of Veterans Affair (VA), the Agency for Healthcare Research and Quality (AHRQ), CMS and the Centers for Disease Control and Prevention (CDC).

SCIP is a comprehensive program, integrated into the quality improvement agenda of the CMS, the Joint Commission the CDC, the American College of Surgeons, the Veterans Health Administration, as well as the other organizations that comprise the SCIP Steering Committee. There are a number of activities underway from these and other partnering organizations.

The SCIP measures are approved by the National Quality Foundation (NQF). Data for many of the SCIP measures are already collected by the Joint Commission for the hospitals it accredits (approximately 85% of hospitals are accredited by the Joint Commission)

We are requesting clearance for set of measures (SCIP and Mortality measures) to be included in the Hospital Reporting Initiative collection of measures of health care quality by CMS. Section 5001(a) of the DRA revises section 501(b) of the MMA legislation. The new legislation eliminates a previous sunset provision associated with the incentive program as established by the MMA and extends the incentive program indefinitely. Therefore, we are requesting an exemption from the requirement to display an expiration date to address the DRA legislation.

Additionally, HCAHPS is not included in this request. CMS published a Federal Register notice soliciting comments on the draft 27-items HCAHPS® Survey in November 2005 (70 FR 67476). The OMB approved the HCAHPS® Survey under OMB control number 0938-0981, with an expiration date of December 31, 2007.

2. Information Users

This information is used by Quality Improvement Organizations (QIOs) 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.

3. Improved Information Technology

CMS is taking advantage of the current interest by hospitals to standardize data collection across the industry as is currently in place for the nursing home and home health arenas. To assist hospitals in this initiative, CMS is employing the use of already established tools for data collection including the CMS Abstraction and Reporting Tool (CART). This is a free tool for hospitals for which CMS will provide training. CMS will continue to offer training on how to use CART. In addition, the Agency is providing 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. 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 Mortality measures this section is not applicable, because all three 30-day Risk Adjusted Mortality measures (heart failure, acute myocardial infarction and pneumonia) can be calculated based solely on Medicare inpatient and outpatient claims 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 Joint Commission for accreditation. As required by statute, CMS is expanding the “starter set” 10 quality measures to include the HQA measures for obtaining the full market basket update under the DRA. HQA-participating hospitals already collect and submit measures on the expanded set. In addition, these measures are required by the Joint Commission for accreditation.

Effective with fiscal year 2008, hospitals will be required to complete and return a written form on which they agree to participate in the RHQDAPU program. This declaration, once signed, will be deemed to remain in effect – even as the set of measures expands or is modified -- until such time as a hospital specifically elects to revoke the pledge.

For the SCIP measures adopted in FY 2007 (SCIP Inf. 2, SCIP VTE 1, SCIP VTE 2) hospitals were required to submit data on these measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2007 (January through March discharges). The deadline for hospitals to submit their data for first quarter is August 15, 2007.

For the new proposed SCIP measures for FY 2009, hospitals will be required to submit data on these measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2008 (January through March discharges). The deadline for hospitals to submit their data for first quarter is August 15, 2008.

For the mortality measures, we propose to use Medicare claims and enrollment data that is already being collected for payment purposes.

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 of care data to be the minimum necessary for data validation and calculation of summary figures to be reliable estimates of hospital performance. To collect the information less frequently would compromise the reliability and validity of any calculated estimates.

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

The emergency 30-day FR notice published on January 25, 2008..

CMS is supported in this initiative by the Joint Commission, National Quality Forum (NQF), and the Agency for Healthcare Research and Quality (AHRQ). These organizations, in conjunction with CMS, will provide technical assistance in developing and/or identifying quality measures, and assist in making the information accessible, understandable, and relevant to the public.

7. 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. No other payments or gifts will be given to respondents for participation.

8. 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.

9. 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.

10. Burden Estimate (Total Hours & Wages)

Section 5001(a) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171) sets out new requirements for the IPPS Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. Under section 1886(b)(3)(B)(viii)(V) of the Act, for payments beginning with FY 2008, we are 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 additional measures that we propose to require for FY 2008.

The burden associated with this section is the time and effort associated with collecting, copying and submitting the data. As part of the Surgical Care Improvement Project (SCIP), we estimate that there will be approximately 3,700 respondents per year. All of these hospitals must submit SCIP Infection 1 and 3 to receive the annual payment update covering FY 2007. Additional surgical procedures covering approximately 6,000,000 discharges annually will be sampled at a 10 percent rate per hospital, so an additional 600,000 discharges will be abstracted and submitted by hospitals for the additional SCIP measures (SCIP Infection 2,4,and 6, and VTE 1, 2). The 10 percent sampling rate is a minimum threshold specified in the most current version of the joint CMS/JC Hospital Quality Measures Specifications Manual. We estimate that it will take 600,000 hours (1 hour per sampled discharge) to abstract and submit data for these additional sampled discharges.

In addition, hospitals must abstract and submit additional information needed for the additional SCIP measures covering the surgical procedures already covered in SCIP Infection 1 and 3. We estimate that about 275,000 discharges will be sampled and abstracted covering these surgical procedures. We estimate that it will take an additional 206,250 hours (3/4 hour per sampled discharge) for hospitals to abstract and submit this additional information. Both estimates include overhead.

In summary, we estimate that it will take the 3700 hospital respondents, a total of 806,250 hours to abstract and submit the SCIP measures. The total number of responses for this information collection request is 3700. This estimate includes overhead.

For the three mortality measures, CMS estimates that there is no additional reporting burden associated with the production of the mortality rates, since the rates are derived using data from Medicare claims that are already submitted by the hospitals for purposes of receiving payment from the Medicare program. No additional data collection or reporting effort is required of the hospitals to derive the rates.

11. Capital Costs (Maintenance of Capital Costs)

There are no capital costs being placed on the hospitals. In fact, successful submission will result in a hospital receiving the full market basket update, while having to expend no capital costs for participation. CMS is providing the data collection tool and an alternative method of data collection to the participants for the submission of data. There are no additional data submission requirements placing additional cost burdens on hospitals.

12. Cost to Federal Government

The cost to the Federal Government is minimal. Hospitals will be reporting data either through the Joint Commission or directly to CMS through CART or QNet exchange. This tool has already been developed and updated for use in the QIO program. There will be no additional costs for development of additional tools. The tools will be revised as needed and updates will be incorporated.

Also, for the mortality 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. We estimate that the annual cost to the Federal Government to derive the measures from the claims data, and to maintain the specifications for all three measures, costs approximately $1.5 million per year.

13. Program or Burden Changes

This program change increases the data collection requirements in order to adhere to Section 1886(b)(3)(B)(viii) of the Act, as recently modified by Section 5001(a) of the DRA. The DRA revises the current hospital reporting initiative; it also stipulates new data collection requirements. The Act also requires that we expand the "starter set" of 10 quality measures that we have used since 2003, and that are currently approved under OCN 0938-0918. In expanding these measures, we must begin to adopt the baseline set of performance measures as set forth in the 2005 report issued by the Institute of Medicine (IOM) of the National Academy of Sciences under section 238(b) of Pub. L. 108-173, effective for payments beginning with FY 2007. The IOM measures include the Hospital Quality Alliance (HQA) measures, the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient perspective survey, and three structural measures.

To comply with the DRA, CMS is expanding the "starter set" 10 quality measures to include HCAHPS® patients' perspectives of care measures as well as surgical care and mortality outcome measures for obtaining the full market basket update.

CMS is to reducing the reporting burden for quality of care information collected by allowing hospitals to submit electronic data in lieu of submitting paper charts, or to utilize electronic data

that they currently report to Joint Commission already for accreditation. Additionally, we anticipate that as hospitals begin submitting electronic abstracted data, there will be less need for CMS to contract with the Clinical Data Abstraction Centers (CDACs) to abstract and submit data electronically.

14. Publication or Burden Changes

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 DRA. 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.

15. Expiration Date

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

16. Certification Statement

We certify that the Hospital Reporting Initiative complies with 5 CFR 1320.9.