

Supporting Statement – Part A
Additional Quality Measures and Procedures for Hospital Reporting of Quality Data for
the FY 2008 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 (JCAHO), 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, the measurement set beyond those measures that we adopted for purposes of the FY 2007 update. This proposed 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. Proposed Additional 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 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

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 JCAHO, the Institute of Healthcare Improvement, the Department of Veterans Affairs (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, JCAHO, 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 collected are National Quality Foundation (NQF) approved. Additionally, this same data is collected by the JCAHO for hospitals accredited by the organization. Approximately 85% of hospitals are accredited by the JCAHO.

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 offers this incentive through fiscal year 2007 and subsequent years. 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 JCAHO 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 measures can be calculated based 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 JCAHO for accreditation. 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 JCAHO for accreditation.

Effective with fiscal year 2008, hospital will be required to complete and return a written form on which they agree to participate in the RHQDAPU program. Hospitals will be required to submit data on the SCIP 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 mortality measures we propose to utilize the claims 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 hospitals, all 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 60-day Federal Register notice was published on October 13, 2006.

The FY 2007 OPPTS Proposed Rule can be found on the CMS website at <http://www.cms.hhs.gov/HospitalOutpatientPPS/HORD/itemdetail.asp?filterType=keyword&filterValue=1506&filterByDID=0&sortByDID=3&sortOrder=descending&itemID=CMS1185569>. Comments are currently being submitted on this notice, and CMS will respond to those comments accordingly.

CMS is supported in this initiative by JCAHO, 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

As with 501(b) of the MMA, for the DRA, hospitals are also 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. 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 and VTE 1, 2). The 10 percent sampling rate is a minimum threshold specified in the most current version of the joint CMS/JCAHO Hospital Quality Measures Specifications Manual. We estimate that it will take 449,500,000 hours (3/4 hour per sampled discharge) to abstract and submit data for these additional sampled discharges.

$6,000,000 \text{ discharges} \times 10\% = 600,000 \text{ discharges sampled}$

$600,000 \text{ discharges} \div 3700 \text{ respondents} = 162.16 \text{ discharges per respondent}$

$3700 \text{ respondents} \times 162.16 \text{ discharges per respondent} = 599,992 \text{ responses per year}$

$599,992 \text{ responses per year} \times .75 \text{ hours per response} = 449,994 \text{ burden hours (approximately 450,000 burden hours)}$

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

137,500 hours (1/2 hour per sampled discharge) for hospitals to abstract and submit this additional information. Both estimates include overhead.

275,000 discharges ÷ 3700 respondents = 74.32 discharges per respondent

3700 respondents x 74.32 discharges per respondent = 274,984 responses per year

274,984 responses per year x .5 hours per response = 137,492 burden hours (approximately 137,500 burden hours)

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

14. Cost to Federal Government

The cost to the Federal Government is minimal. Hospitals will be reporting data either through the JCAHO 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.

15. Program or Burden Changes

This program change increases the data collection requirements in order to adhere to 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 JCAHO 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.

16. 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.

17. 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.

18. Certification Statement

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