Supporting Statement for Hospital Reporting Initiative—Hospital Quality Measures and Supporting Regulations in Section 5001(a) Deficit Reduction Act a revision of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

A. Background

The recently enacted section 5001(a) of the Deficit Reduction Act sets out new requirements for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program. The RHQDAPU program was established to implement section 501(b) of the MMA of 2003. The DRA 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 provided to Medicare beneficiaries. In implementing the DRA provisions, hospitals may choose to participate in the voluntary hospital reporting initiative. Effective with payment beginning with FY 2007, hospitals that choose to participate in the RHQDAPU program agree to meet RHQDAPU program requirements rather than receive a reduction of 2.0 percent points in their Medicare Annual Payment Update. Hospitals that choose not to participate in the RHQDAPU program will receive a reduction of 2.0 percent points in their Medicare Annual Payment Update.

At a press conference on December 12, 2002, Secretary Tommy Thompson announced steps HHS and partners (see below) were taking for public reporting of hospital quality information. The public reporting began in July 2003 with a professional website with plans to roll out a consumer website. Secretary Thompson described the information on the consumer website as "an important tool for individuals to use in making decisions about their health care coverage". Data from this initiative populates the Hospital Compare Web site, which debuted in April 2005, and is located at www.hospitalcompare.hhs.gov. Hospital Compare, is a new website/web tool developed to publicly report valid, credible and user-friendly information about the quality of care delivered in the nation's hospitals. This initiative continues to be a priority today to both the Secretary and to the Centers for Medicare & Medicaid Services (CMS).

In addition, there is a growing consensus among a broad array of federal, state, business, industry, union, employer, and consumer stakeholders around the importance of public reporting of hospital quality measures, including those that measure clinical outcomes and the patient's perception of care. The stakeholders believe that over time, public reporting of these hospital quality measures will not only give consumers needed information about the health care system that may assist them in making more informed decisions about their care. But it will also provide valid, reliable, comparable and salient quality measures as a stimulus for clinicians and providers to improve the quality of the care. This reporting initiative has become a significant step toward informing the public about quality care, and sustaining health care quality improvement for Medicare beneficiaries.

Initially, section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provided a monetary incentive for eligible hospitals to participate in the public reporting initiative. The law required hospitals to submit quality data on all 10 quality measures "starter set" in order to receive the full update each fiscal year. The law provided for a reduction of 0.4 percentage points to the update percentage increase for any hospital that did not submit the data for the ten quality measures for FY 2005, 2006, and 2007.

The DRA revises the current hospital reporting initiative. It stipulates new data collection requirements. The law provides a 2.0 percent reduction points to the update percentage increase for any hospital that does not submit the quality data in the form, and manner, and at a time, specified by the Secretary. The Act also requires that we expand the "starter set" of 10 quality measures that we have used since 2003. To comply with these new requirements we must make changes to the Hospital Reporting Initiative.

This collection originally received emergency clearance approval with change on June 1, 2004, with an expiration date of October 31, 2004. Approval on a second PRA package was received on 12/22/05 to 12/31/08. This collection will be an on-going effort by CMS, the Secretary, and other agencies and organizations

B. Justification

1. Need and Legal Basis

The Hospital Reporting Initiative is supported by the American Hospital Association, the Federation of American Hospitals, and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The measures collected are National Quality Foundation (NQF) approved. The specific measures are listed on the CMS website at http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalHQA2004_20070200512.pdf. 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 a revision to the existing clearance for 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 2008. Therefore, we are requesting an exemption of displaying an expiration date to address the DRA legislation.

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 does not plan to use focus groups or market testing at this time.

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.

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 2007, hospital will be required to complete and return a written form on which they pledge to submit data on a expanded set of quality measures (anticipated 21 measures), starting with discharges that occur in calendar year 2006. Hospitals will be required to submit data on the expanded measures to the QIO Clinical Warehouse beginning with discharges that occur in the first calendar quarter of 2006 (January through March discharges). The deadline for hospitals to submit their data for first quarter is August 15, 2006.

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 June 2, 2006, see attached.

A Federal Register Notice is anticipated to be published on August 1, 2006. The FY 2007 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 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.

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)

The burden estimate has been updated based on anticipated levels of participation by hospitals. We estimate that there will be approximately 3,700 respondents per year. Of this number, approximately 3,100 hospitals are JCAHO accredited and are currently collected measures and submitting data to the JCAHO on a quarterly basis. Of the JCAHO accredited hospitals, approximately 1,080 are collecting the same measures CMS will be collecting for public reporting. Therefore, there will be no additional burden for these hospitals. About 1940 of the JCAHO accredited hospitals will need to collect an additional topic (SCIP) in addition to the data already collected for maintaining JCAHO accreditation. About 60 accredited hospitals do not submit for the current three starter set topics, and must begin collecting and submitting data on all four topics. In addition, there are approximately 600 hospitals that do not participate in the JCAHO accreditation process. These hospitals will have the additional burden of collecting data on all four topics.

For JCAHO hospitals, we estimate it will take 25 hours per quarter per topic for collection. We expect the burden for hospitals to total 238,560 hours per year, including time allotted for overhead. For non-JCAHO accredited hospitals, we estimate the burden to be 246,000 hours per year. This estimate also includes overhead. The total number of burden hours for all hospitals combined is 484,560 hours. The number of responders will vary according to the level of voluntary participation. One hundred percent of the data may be collected electronically. There will be no additional burden placed on hospitals that submit this data in response to Section 5001(b) of the DRA.

The additional third party disclosure burden is estimated to total 99,200 hours, with an average 8 hours per quarter per hospital, or 32 hours annually per hospital for an estimated 3,100 hospitals using third party vendors. Duties of these vendors include submitting data into the CMS QIO clinical warehouse, reviewing submission reports, and administrative requirements necessary to submit data to CMS.

The total burden associated with this information collection request is 3700 respondents, 14,800 responses, and 583,760 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.

12. 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.

13. 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. 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 the HQA measures for obtaining the full market basket update. Hospitals participating in the HQA already collect and submit data on the expanded set. In addition, these measures are also required by the JCAHO for accreditation. For both the HQA and JCAHO, hospitals are currently submitting this information on a quarterly basis to maintain their accreditation status. Those hospitals not currently submitting data on the expanded set will be required to begin collecting and reporting.

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 Abstracting 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.

C. Collection of Information Employing Statistical Methods

1. Describe potential respondent universe.

All acute care hospitals in the United States constitute the potential respondent universe. This includes approximately 3,929 hospitals.

2. Describe procedures for collecting information.

Electronic abstracted data from clinical charts will be submitted via a secure Web site (QIOnet). Electronic data conforming to a specified format will be collected in a secure Oracle-based relational database.

3. Describe methods to maximize response rates.

To maximize response rates, the DRA provides payment incentives for participation in public reporting. In addition, CMS is providing technical assistance to any hospitals requiring assistance with the submission tools.

4. Describe any tests of procedures or methods.

After the initial submission of data to receive the market basket update (fiscal years 2006 and 2007), CMS established validation requirements for all submitted data. This information has been provided to hospitals prior to implementation.

5. Provide name and telephone number of individuals consulted on statistical aspects.

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