Supporting Statement for Collection of HEDIS® Data

PURPOSE:

The purpose of this report is to transmit the Center for Medicare & Medicaid Services (CMS) supporting statement for a request to the Office of Management and Budget (OMB) for the revision of a currently approved collection, under the Paperwork Reduction Act and 5 CFR 1320.6. The information request relates to the collection of quality of care indicators from Medicare Advantage Organizations and §1876 cost contracting managed care organizations (MCOs) as well as demonstration contracts.

BACKGROUND:

CMS has a responsibility to its Medicare beneficiaries to require that care provided by managed care organizations under contracts to CMS is of high quality and conforms to currently accepted standards of medical care. One way of ensuring high quality care in MCOs is through the development of standardized clinical performance measures and beneficiary surveys to enable CMS to gather the data needed to evaluate the care provided to Medicare beneficiaries.

In December 1997, OMB approved the request from CMS for the information collections under HEDIS® and assigned the agency form number CMS-R-200. The collections approved under that request included the HEDIS® collection (following the technical specifications contained in Volume 2, published by the National Committee for Quality Assurance (NCQA); the Health of Seniors/Health Outcomes Survey (HOS); and the Medicare CAHPS® survey. Since that approval there has been a change in statutory authority as a result of the Balanced Budget Act of 1997. During the latter part of 2000, CMS instituted several policy changes regarding this collection which reduced burden substantially on the part of the MCOs and the process for finalizing and publishing that policy delayed the request for OMB approval. In addition, the renewal of OMB authority for the Medicare CAHPS survey was completed as a separate request. The HOS renewal was also submitted separately. **This request is solely for a renewal of approval for the HEDIS collection.** In November and December of 2006, the transition of the HEDIS contract from one operating component to another (OCSQ to CBC) resulted in the delay in filing of a package for re-approval of the HEDIS® collection until the final week of January 2007.

CMS is committed to the implementation of health care quality assessment and improvement strategies in the Medicare Advantage (MA) program. In January 1997, CMS began requiring Medicare managed care organizations (MCOs) to collect and report performance measures from the Health Employer Data and Information Set (HEDIS) relevant to the Medicare managed care beneficiary population. HEDIS® is a widely used set of health plan performance measures utilized by both private and public health care

purchasers to promote accountability and to assess the quality of care provided by managed care organizations. HEDIS® is designed for private and public health care purchasers to promote accountability and to assess the quality of care provided by managed care organizations. Originally designed for private employers' needs as purchasers of healthcare, HEDIS® has been adapted for use by public purchasers, government compliance monitors, and managed care consumers. HEDIS® is developed and maintained by the National Committee for Quality Assurance (NCQA) in collaboration with CMS and other representatives of purchaser, managed care industry, provider/practitioner and health services research communities

CMS is preparing for a 10th round of HEDIS® data collection (HEDIS measurement year 2006 – reporting year 2007). HEDIS® 2007 is the latest edition of the measure set, which contains 52 measures across 8 domains of care (Effectiveness of Care, Access/Availability of Care, Satisfaction with the Experience of Care, Health Plan Stability, Use of Services, Cost of Care, Informed Health Care Choices and Health Plan Descriptive Information). Certain measures are collected via the HOS and CAHPS surveys.

The HEDIS® data will help CMS assess its managed care contractors' performance, and will allow beneficiaries to evaluate and compare health plans using public displays which use this and other performance information. HEDIS® is a crucial part of CMS' quality assurance strategy. Current law authorizes Quality Improvement Organizations (QIOs) to review the quality of care provided to Medicare beneficiaries. HEDIS® data is used by QIOs to focus quality improvement activities more efficiently and effectively, as the data will provide plan overview information in a manner not previously achievable. Comparison among plans will be facilitated and remedial activities more precisely targeted.

The 2007 standard reporting requirements for Medicare Managed Care Organizations, which include HEDIS®, are contained in the Medicare Managed Care Manual Chapter 5: Quality Assurance. HEDIS is one of three measurement sets collected prior to November 2003 (HEDIS®, CAHPS®, HOS), that CMS is authorized to collect under MMA 722 without first submitting a report to Congress containing justification and industry recommendations. It is unlikely that there will be material changes to this policy over the next several years.

A. JUSTIFICATION

1) Need and Legal Basis

Statutory and Regulatory Basis

Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33) added sections 1851 through 1859 to the Social Security Act to establish a new Part C of the Medicare program, known as the "Medicare+Choice" program. The existing Part C of the statute, which included provisions of section 1876 governing existing Medicare HMO

contracts, was redesignated as Part D. The implementing regulations of the Act that relate to quality assurance and performance measurement are contained in Subpart D of part 422. These requirements implement and are based on the provisions of section 1852(e) of the Act and also incorporate the requirements of section 1851 (d)(4)(D), which provides that the information made available to Medicare beneficiaries for plan comparison purposes should include plan quality and performance indicators, to the extent available.

These statutory and regulatory requirements are also contained within the contract signed with CMS by the MCO. The relevant statutory and regulatory sections pertaining to HEDIS® are shown below:

I. Social Security Act Title 18 Sec. 1852 e 3 A i:

(e) QUALITY IMPROVEMENT PROGRAM.—

(1) IN GENERAL.—Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan (other than MSA plans) offered by such organization (other than an MA private fee-for-service plan or an MSA plan).
(2) CHRONIC CARE IMPROVEMENT PROGRAMS.—As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.
(3) DATA.—
(A) COLLECTION, ANALYSIS, AND REPORTING.—
(i) IN GENERAL.—Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality.

II. MMA 722 :

3) DATA. —

(A) COLLECTION, ANALYSIS, AND REPORTING. —

(i) IN GENERAL. — Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality.
(ii) APPLICATION TO MA REGIONAL PLANS. — The Secretary shall establish as appropriate by regulation requirements for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality for MA organizations with respect to MA regional plans. Such requirements may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans.
(iii) APPLICATION TO PREFERRED PROVIDER ORGANIZATIONS. — Clause (i) shall apply to MA organizations with respect to MA local plans that are pre- ferred provider organization plans only insofar as services are furnished by providers or services, physicians, and

other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.
(iv) DEFINITION OF PREFERRED PROVIDER ORGANIZATION PLAN. — In this subparagraph, the term 'preferred provider organization plan' means an MA plan that

(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;
(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and
(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(B) LIMITATIONS. —

(i) TYPES OF DATA. — The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.
(ii) CHANGES IN TYPES OF DATA. — Subject to sub- clause
(iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organi- zations and private accrediting bodies.
(iii) CONSTRUCTION. — Nothing in the subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1851(d)(4)(D).;

III. 42 CFR §422.152(b)(3)

(b) Requirements for MA coordinated care plans (except for regional MA plans and including local PPO plans that are offered by organizations that are licensed or organized under State law as HMOs.
An MA coordinated care plan's (except for regional PPO plans and local PPO plans as defined in paragraph (e) of this section) quality improvement program must –

(1) In processing requests for initial or continued authorization of services, follow written policies and procedures that reflect current standards of medical practice.

(2) Have in effect mechanisms to detect both underutilization and overutilization of services

(3) Measure and report performance. The organization offering the plan must do the following:
(i) Measure performance under the plan, using the measurement tools required by CMS, and report its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.
(ii) Make available to CMS information on quality and outcomes measures that will enable beneficiaries to compare health coverage options and select among them, as provided in § 422.64

Need

The collection of HEDIS® is necessary to hold Medicare managed care contractors accountable for delivering care in accordance with widely accepted clinical guidelines and standards of care. This reporting requirement measures the extent to which plans are providing care according to these standards, and allows CMS to obtain the information necessary for the proper oversight of the program. It is critical to CMS' mission that we collect and disseminate information that will help beneficiaries choose among health

plans, contribute to improved quality of care through identification of quality improvement opportunities, and assist CMS in carrying out its oversight responsibilities.

2) Information Users

The data are used by CMS staff to monitor MCO performance, inform audit strategies, inform beneficiary choice through their display in CMS' consumer-oriented public compare tools and websites. MCOs use the data for quality assessment and as part of their quality improvement programs and activities. Quality Improvement Organizations (QIOs), and CMS contractors, use HEDIS® data in conjunction with their statutory authority to improve quality of care, and consumers who are making informed health care choices. In addition, CMS makes health plan level HEDIS® data available to researchers and others as Public Use Files on the CMS website www.cms.hhs.gov.
CMS also makes HEDIS® data available to Medicare beneficiaries on its consumer website (www.medicare.gov) and in print materials available through the toll-free consumer phone line, upon request. CMS also makes some of its internal analyses for monitoring and audit purposes available to MA contractors (can only see their own data) and to Regional Offices through the secure Health Plan Management System (HPMS). The use of this data to inform and educate Medicare beneficiaries and their caregivers is a high priority of this current Administration.

3) Improved Information Technology

There are no barriers or obstacles that prohibit the use of improved technology for this information collection activity. The HEDIS® measures are reported through NCQA's Web-Based Interactive Data Submission System (IDSS) that includes many automation and quality control features permitting importing of data, pre-populated fields, and built-in edit checks. Previously, an Excel based tool was used for this purpose. Each year there have been improvements to the data submission process making it easier, simpler, and less burdensome to plans to prepare and submit HEDIS® data.

4) Duplication and Similar Information

MCOs have been submitting HEDIS® data to CMS since 1997. NCQA estimates that more than 80% of MCOs are collecting some or all of the HEDIS® data for their commercial and/or Medicaid populations. Most MCOs that contract with CMS under a Medicare contract also have a commercial population and collect HEDIS® as a result of seeking NCQA accreditation for their commercial enrollment. In recent years, we have seen an increase in the number of MCOs that seek accreditation from NCQA for their Medicare product line (this is a voluntary business decision, and not a CMS contract requirement) and thus are able to use the CMS-required Medicare HEDIS® collection for more than one purpose. Thus, the incremental costs of doing HEDIS® for the Medicare population is small relative to the fixed costs that MCOs have invested in to do it for the commercial business. In addition, starting with 1999, CMS revised its policy regarding auditing of data. In prior years, CMS required a partial audit using the terminology of NCQA. We reviewed the operational impact of that decision and discussed it with

MCOs to contract with audit firms for a "full audit". We decided that the full audit methodology, which extrapolates from a core measure set to the entire set of measures submitted for all product lines, commercial, Medicare and Medicaid, enabling CMS to be assured that the data are valid and also enables greater flexibility and a more cost-effective approach to contracting and paying for the audit.

5) Small Business

The burden on small MCOs is reduced by requiring a standardized and commonly accepted measure set in the managed care industry, with which MCOs can meet requirements of Medicare and many private purchasers for reporting performance. There is no way to further reduce the burden and still collect the necessary information.

6) Less Frequent Collection

CMS collects the HEDIS® data annually. The MCOs must retain the data for 6 years. To collect data less frequently would actually increase burden because we would lose the efficiencies gained by using a standardized, industry accepted and commonly used measurement set which makes it possible for MCOs to meet the data reporting requirements of Medicare and other private purchasers using the same instrument and submission process. In addition, contracts between CMS and MCOs are renewable on an annual basis, so we need this performance data for program management and contracting decisions. It is also used to help Medicare beneficiaries and their caregivers make decisions about which health plan to choose, each year during open enrollment season.

7) Special Circumstances

The publicly reported data that CMS makes available will not identify beneficiaries in any way. The HEDIS patient level file is available only to requesters who for confidentiality reasons must sign a Data Use Agreement with CMS and must meet CMS' data policies and procedures that include, but are not limited to, submitting a research protocol and study purpose. For information about Data Use Agreements, contact the Division of Data Liaison and Distribution, Enterprise Database Group, within CMS' Office of Information Services.

8) Federal Register Notice/Outside Consultation

The 60-day Federal Register notice for this information collection request published on February 16, 2007.

9) Payment/Gifts to Respondents

There are no provisions to provide any payment/gift.

10) Confidentiality:

All patient-level data are protected from public dissemination in accordance with the Privacy Act of 1974, as amended.

11) Sensitive Questions

The HEDIS® measurement set does not contain any sensitive questions, rather it is collected from health plan administrative data and medical record review.

12) Estimates of Burden Hours and Wages

Starting with HEDIS® 2001 (for measurement year 2000), CMS substantially reduced the reporting burden on MCOs due to the change in policy regarding the reporting unit. In prior years, MCOs reported once for each contract number unless CMS divided the contract service area into "Market areas" where the contract service are covered more than one major community or city and each market area had at least 5,000 Medicare enrollees. Reporting units were known as "contract-markets". Due to changes in an MCO's contract service area from year to year and other factors, this market area approach to reporting was not a completely stable unit for longitudinal analysis nor was it completely comparable within a contract year across MCOs in an area. The Balanced Budget Act and ensuing regulations and policy have significantly impacted the service area configurations of MCOs such that MCOs have consolidated multiple noncontiguous contracts within a state for the 2001 contract year. After extensive analysis and deliberation among all components that collect and utilize quality and satisfaction data from MCOs, the sampling and reporting unit for HEDIS® have been changed. In 2003 and thereafter, MCOs have one reporting unit for HEDIS® for each MA contract with CMS. This aligns HEDIS® reporting with the level at which MCO performance is monitored, quality improvement projects are performed, and chronic care improvement programs are evaluated, i.e.: at the contract-level. This reporting unit policy achieves significant burden reduction and standardization.

In addition, the BBA requires CMS to report comparative quality and satisfaction information for managed care and fee-for-service in a manner not previously required. In order to minimize reporting burden, the MMA section 722 allows CMS to pursue collection of other measurement sets from MA plans that were not already being collected prior to November 2003 only after submitting a report to Congress for approval which contains cost/benefit/burden analyses and industry feedback. HEDIS® is one of three measurement sets currently collected by CMS from MA plans which were already being collected prior to November 2003.

Based on Industry estimates, we believe the average time per MCO for obtaining and reporting Medicare specific measures to be 48 hours per MCO. Therefore, 48 hours per MCO x 705 responding MCOs = 33,840 hours.

Estimated Cost: 33, 840 hours x $40/hour =$1,353,600. This estimate is likely to be slightly overstated since most MCOs produce HEDIS® data for multiple product lines

(Medicare, Medicaid, and Commercial enrollment), and the Medicare portion may be a marginal addition to the data collection costs that are borne by the MCOs as a part of their voluntary accreditation activity with NCQA.

13) Capital Costs.

There are no capital costs.

14) Costs to Federal Government

There are no contract costs to the Federal government in terms of its contracts with NCQA to administer the annual HEDIS® data collection. Contract costs for HEDIS® data collection is $600,000. CMS personnel involved in HEDIS® include approximately one FTE at the GS 13/14 level.

15) Program and or Burden Changes

The last time this package was submitted for OMB approval, OMB approved 351,520 hours for HEDIS®. We are now requesting 33,840 hours, which is a decrease from our last request. The changes for annual responses, annual hour burden and annual cost burden, reflect a correction to the numbers reported for the prior PRA submission approved in January 2004, as well as a real change in estimated burden. The 2004 submission combined requests for HEDIS® and HOS.

This current submission is only for HEDIS® and is being filed as a new submission. In 2004 there were 169 entities that were required to respond with HEDIS data because they contracted to provide Medicare managed care services. With the passage and implementation of the Medicare Prescription Drug, Improvement and Modernization Act, several hundred entities received contracts to provide Medicare Part D services, bringing the number of respondents up to 705. The annual hour burden decreased substantially because the amount of time it takes to respond to the HEDIS survey has been greatly reduced and more accurate data on the time needed to complete a response was gathered.

Thus, with 705 respondents taking 48 hours each to complete the survey at a cost of $40 an hour, the annual hour burden is 33,840, the cost per response is $1,920 for a total annual cost burden of $1,353,600

16) Publication and Tabulation

HEDIS® data has been published in beneficiary information products since 1998 and has consistently been contained in more CMS information products over time. CMS makes HEDIS® data available to Medicare beneficiaries on its consumer web-site (www.medicare.gov) and in print materials available through the toll-free consumer phone line, upon request. In the Fall of 2007, more of this information will be made available through the beneficiary website in an enhanced comparison tool. CMS makes industry trends (national, regional and state percentiles) using this data available to health

plans via the Health Plan Management System (HPMS). In addition, CMS makes health plan-level HEDIS® data available to researchers and others as Public Use Files on the CMS website (www.cms.hhs.gov).

17) Expiration Date

The collection of HEDIS® is an ongoing endeavor. Therefore, an expiration date is not practical.

18) Certification Statement

There are no exceptions to this certification statement.

B. Collection of Information Employing Statistical Methods – HEDIS®

The HEDIS® collection uses the same statistical methods described in the original request. There are six Medicare measures that may be collected using what is referred to as the "hybrid" method for reporting. Rather than reporting the entire eligible population using the administrative database information, the MCO uses statistical sampling with each sample being no larger than 411. Medical record review is conducted for this sample to supplement information which may be incomplete or unavailable in administrative data sources (i.e.: lab values). The measures for which using the hybrid method is optional currently are: colorectal cancer screening, beta blocker treatment after heart attack, cholesterol management for patients with cardiovascular conditions, and comprehensive diabetes care. The only measure for which the hybrid collection methodology is required is: controlling high blood pressure. Complete information regarding the guidelines for calculations and sampling is available in NCQA's publication HEDIS® 2007, Volume 2 Technical Specifications (See Attachment). These are the same methods previously used and are the current standard for both the Medicare enrollment collection and the HEDIS® data collection for the commercial enrollment of MCO. Since these measures are not derived from a survey, response rates are not an issue.