Part A: Supporting Statement
CMS-10219, OMB Number 0938-1028
HEDIS® Data Collection for Medicare Advantage

PURPOSE:

The Centers for Medicare & Medicaid Services (CMS) is requesting a renewal of Office of Management and Budget (OMB) number 0938-1028, that expires November 30, 2010, for the currently approved collection of Healthcare Effectiveness Data and Information Set (HEDIS®) data for managed care contracts which are now called Medicare Advantage. This request for a renewal is supported under the Paperwork Reduction Act and 5 CFR 1320.6. Medicare Advantage Organizations (MAOs) and §1876 cost contracting managed care are required to submit HEDIS® data to CMS on an annual basis. Sections 422.152 and 422.516 of Volume 42 of the Code of Federal Regulations (CFR) specify that Medicare Advantage organizations must submit performance measures as specified by the Secretary of the Department of Health and Human Services and by CMS. These performance measures include HEDIS®.

BACKGROUND:

CMS has a responsibility to its Medicare beneficiaries to require that care provided by Medicare Advantage organizations (MAOs) is of high quality and conforms to currently accepted standards of medical care. One way of ensuring high quality care in MAOs is collection, monitoring and reporting quality data indicators to the public. The reporting of quality data is not only beneficial to the public by supporting transparency, but it also is contributing to quality improvement in Medicare Advantage.

CMS is committed to the implementation of health care quality assessment in the Medicare Advantage program. In January 1997, CMS began requiring Medicare managed care organizations (MCOs) (these organizations are now called Medicare Advantage organizations or MAOs) to collect and report performance measures from 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 since been adapted for use by public purchasers. 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. Commercial, Medicare and Medicaid plans pay for the auditing of their HEDIS® data.

CMS is now in its 13th round of HEDIS® data collection (HEDIS measurement year 2009 – reporting year 2010). HEDIS® 2010 is the latest edition of the measure set, which contains 76 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, Health Plan

Descriptive Information, and Informed Health Care Choices). Certain of the HEDIS® measures are collected through the CAHPS and HOS surveys and are part of separate OMB approval numbers. The following table (Table 1) shows the HEDIS® measures that are required for Medicare Advantage organizations (see Attachments for Technical Specifications) for the Medicare program in 2010, as compared with 2007.

Table 1: HEDIS® Measures for Medicare in 2007 and 2010 (Crosswalk Comparison Table)

	HEDIS Measures for Reporting	HEDIS Measures In 2007	HEDIS Measures In 2010
	Effectiveness of Care		
ABA	Adult BMI Assessment		X
BCS	Breast Cancer Screening	X	X
COL	Colorectal Cancer Screening	X	X
GSO	Glaucoma Screening in Older Adults	X	X
COA	Care for Older Adults (SNP-only measure)	X	X
SPR	Use of Spirometry Testing in the Assessment and Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)	X	X
PCE	Pharmacotherapy Management of COPD Exacerbation	X	X
CMC	Cholesterol Management for Patients with Cardiovascular Conditions	X	X
CBP	Controlling High Blood Pressure	X	X
PBH	Persistence of Beta-Blocker Treatment After a Heart Attack	X	X
CDC	Comprehensive Diabetes Care	X	X
RDI	Relative Resource Use for People With Diabetes	X	
OMW	Osteoporosis Management in Women Who Had a Fracture	X	X
AMM	Antidepressant Medication Management	X	X
FUH	Follow-up After Hospitalization for Mental Illness	X	X
MPM	Annual Monitoring for Patients on Persistent Medications	X	X
DDE	Potentially Harmful Drug-Disease Interactions in the Elderly	X	X
DAE	Use of High-Risk Medications in the Elderly	X	X
MRP	Medication Reconciliation Post-Discharge (SNP-only measure)	X	X
	Access /Availability of Care		
AAP	Adults' Access to Preventive/Ambulatory Health Services	X	X
IET	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment	X	X
CAB	Call Abandonment	X	X
CAT	Call Answer Timeliness	X	X
	Health Plan Stability		
TLM	Total Membership	X	X

1

HEDIS Measures for Reporting		HEDIS Measures In 2007	HEDIS Measures In 2010
Use of Services[2]			
FSP	Frequency of Selected Procedures	X	X
CIPA	Chemical Dependency Utilization-Inpatient Discharges And Length of Stay	X	
IPU	Inpatient Utilization --- General Hospital/Acute Care	X	X
AMB	Ambulatory Care	X	X
NON	Inpatient Utilization-Non-Acute Care	X	X
MPT	Mental Health Utilization	X	X
IAD	Identification of Alcohol and Other Drug Services	X	X
ORX	Outpatient Drug Utilization	X	X
ABX	Antibiotic Utilization	X	X
Health Plan Descriptive Information			
BCR	Board Certification	X	X
ENP	Enrollment by Product Line	X	X
EBS	Enrollment by State	X	X
RDM	Race/Ethnicity Diversity of Membership	X	X
LDM	Language Diversity of Membership	X	X

The HEDIS® data helps CMS assess its managed care contractor performance, and beneficiaries to evaluate and compare health plans as part of the plans' ratings on www.medicare.gov. HEDIS® is a crucial part of CMS' quality assurance strategy. HEDIS® data are used to focus quality improvement activities more efficiently and effectively.

JUSTIFICATION

(1) Need and Legal Basis

The collection of quality measures is required as part of Section 1852 (e), MMA 722 and 42 CFR § 422.152 (b) (3).

Statutory and Regulatory Basis

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

(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 PROGRAM.— 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

2

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 subclause

(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:

Measure performance under the plan, using the measurement tools required by CMS, and reports its performance to CMS. The standard measures may be specified in uniform data collection and reporting instruments required by CMS.
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 Advantage 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 MAO performance and inform audit strategies, and inform beneficiary choice through their display in CMS' consumer-oriented public compare tools and websites. Medicare Advantage organizations 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 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.

(3) Use of 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 of Efforts

As stated previously above, MAOs have been submitting HEDIS® data to CMS since 1997. NCQA estimates that more than 80% of MAOs are collecting some or all of the HEDIS® data for their commercial and/or Medicaid populations. Most MAOs 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, there is an increase in the number of MAOs that seek accreditation from NCQA for their Medicare product line (this is a voluntary business decision rather than 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 are small relative to the fixed costs that MAOs have invested in it to do it for the commercial business.

(5) Small Businesses

The burden on small MAOs is reduced by requiring a standardized and commonly accepted measure set in the managed care industry, with which the contracts can meet requirements of Medicare and many private purchasers at the same time 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. 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 MAOs 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 MAOs 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.

(8) Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was posted on June 18, 2010, no comments were received.

(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.

(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) Burden Estimate (Hours and Wages)

In Table 1, there are 38 HEDIS measures listed for both the years of 2007 and 2010. Only three of these measures differ in the crosswalk. The measure ABA, Adult BMI Assessment, is new in the year 2010 (it was not used in 2007 for MA plans). The two measures of RDI, Relative Resource Use for People with Diabetes, and CIPA, Chemical Dependency Utilization-Inpatient discharges and Length of Stay, were collected in 2007 but are not used in 2010. **The HEDIS contractor, NCQA was consulted about the impact of decreasing the data collection by one measure, and NCQA felt that the differences with these measures in burden were negligible for the hours and costs.**

CMS is presenting a much higher burden estimate and cost with this PRA package in 2010 compared with the current package which was approved in 2007. CMS believes that the 2010 package contains the realistic burden and cost for HEDIS because we relied on NCQA for information and they in turn received concrete information from the contracts.

The following was stated in the 2007 PRA package, which expires 11/30/10:
"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."

For this 2010 PRA package, CMS has consulted with NCQA about the burden and costs of obtaining HEDIS data for the 483 MAOs. CMS found that the burden (hours) were significantly

underestimated in the 2007 package. However, CMS has found that the hourly rate may be lower for the HEDIS® data collection, because the contracts need the services of two individuals for the HEDIS® work: one is a Computer Support Specialist, which the Bureau of Labor Statistics reports has an hourly rate of $21.02 an hour, and one is a Medical Records Review Technologist, which the Bureau of Labor Statistics reports has an hourly rate of $24.94 an hour. The Computer Support Specialist will pull administrative data from electronic files, and will need an estimated 80 hours to perform the work of the annual HEDIS® data needed for the contract's submission. The Medicare Records Review Technologist will need to review medical records of plan members and will need 240 hours to perform the work of the annual HEDIS® data needed for the contract's submission.

The total hours for the Computer Support Specialists is 80 hours x 483 contracts = 38,640 hours. The total hours for the Medical Records Review Technologists will be 240 hours x 483 contracts = 115,920 hours.

Therefore, the total hours needed by all the contracts = 38,640 hours + 115,920 hours = 154,560 hours for 483 contracts.

The 2010 costs to the contracts that involve burden (hours) as well, are as follows:
For the Computer Support Specialist position, at $21.02 an hour for 80 hours, the cost is $1,682 a contract, or $812,213 for 483 contracts. For the Medical Records Review Technologist position, at $24.94 an hour for 240 hours, the cost is $5,986 a contract, or $2,891,045 for 483 contracts. Therefore, the total cost for one contract is $7,668 and the total cost for 483 contracts is $3,703,258.

Concerning cost of the HEDIS® data collection effort, it is noted that in the 2007 package it was stated that the total cost for one contract was $1,920. However, that was only for 48 hours. If we multiply $1,920 by 6 (to account for what would the cost be for 240 hours, rather than for 48 hours), then the cost for each contract would have been $11,520. We believe that our estimates in 2010 are fair and more realistic than in the previous package. The final total cost to all 483 contracts, is $3,703,258 (the contracts' own labor costs).
See Table 2 for a break-out of HEDIS® data collection for the costs.

TABLE 2: HEDIS® Data Collection Hours and Costs for 2010

Category	Number of MA Contracts	Total Burden Hours	Average Hourly Wage Rate*	Estimated Data Collection Cost to Respondents	
Computer Support Specialist	483	80	$21.02	$812,213	
Medical Records Reviewer	483	240	$24.94	$2,891,045	
Total	483	154,560	N/A	$3,703,258	

(13) Capital Costs

In Table 2 above, we included the costs of the Independent Auditor for each of the MA plans. We believe that this cost could be distinguished as "Capital Costs" in this package.
In 2007, the PRA package did not include the auditing costs. For this 2010 PRA package, we are including the auditing costs. The total cost of having the data audited, for each contract is $15,000 for the Medicare product line only. This information was obtained from NCQA (contracts pay at least $30,000 for their three product lines of Medicare, Medicaid and Commercial). Therefore, the total cost of data auditing for all 483 contracts is $15,000 x 483 = $7,245,000.

The final total cost to all 483 contracts, is $3,703,258 (the contracts' own labor costs) plus the auditing costs (contracts have to pay outside independent auditors) of $7,245,000, equals a total cost of $10,948,258. It will cost each contract $22,667.

Independent Auditor	483	N/A	$15,000 (in all)	$7,245,000

(14) Cost to Federal Government

Federal contract costs for HEDIS® data collection is $565,000 annually. CMS personnel involved in HEDIS® include approximately one FTE at the GS-13 level.

(15) Changes to Burden

In Table 1, there are 38 HEDIS measures listed for both the years of 2007 and 2010. Three of these measures differ in the crosswalk. The measure ABA, Adult BMI Assessment, is new in the year 2010 (it was not used in 2007 for MA plans). The two measures of RDI, Relative Resource Use for People with Diabetes, and CIPA, Chemical Dependency Utilization-Inpatient discharges and Length of Stay, were collected in 2007 but are not used in 2010. The HEDIS contractor, NCQA was consulted about the impact of decreasing the data collection by one measure, and NCQA felt that the difference in burden was negligible. No new methods or procedures will be tested during HEDIS® collection. However, each year after the HEDIS collection cycle has been completed, NCQA analyzes the level of comparability of rates collected using the administrative methodology and the hybrid collection methodology in order to ensure continuing validity and reliability between the two collection methodologies.

CMS is presenting a much higher burden estimate and cost with this PRA package in 2010 compared with the current package which was approved in 2007. CMS believes that the 2010 package contains the realistic burden and cost for HEDIS because we relied on NCQA for information and they in turn received concrete information from the contracts.

Overall, the changes from 2007 to 2010 are as follows: there were 705 contracts in 2007 and 483 contracts in 2010, so there are 222 less contracts in 2010. CMS realizes that there are many fewer contracts in 2010 than in 2007 and that the hours and the costs are much higher in 2010. CMS realizes that the prior package did not fully account for the work that is entailed in the data collection and in the auditing function that is necessary to account for the accuracy of the data that is collected by the MA contracts.

The number of hours to do the HEDIS® data collection was much lower in 2007 (33,840 hours) than we have in this package for 2010 (154,560 hours). The difference is 154,560 hours minus 33,840 hours is 120,720 hours. Therefore, in 2010 we are increasing the number of hours by 120,720 hours. However, the hourly rate of the persons to do the work is far less in 2010 than it was estimated in 2007. In 2007, the hourly rate was $40 an hour for 48 hours. By comparison, in 2010, the hourly rate is $21.02 for 80 hours and $24.94 for 240 hours.

In this 2010 package, we are stating that the total hours needed by 483 contracts = 38,640 hours + 115,920 hours = 154,560 hours. In the 2007 package it was stated that the total number of hours = 33,840 hours for 705 contracts. Therefore, we are increasing the number of hours for a much smaller number of total respondents (it was 705 in 2007 and it is 483 in 2010).
In this 2010 package, the total cost for one contract is $7,668 and the total cost for 483 contracts is $3,703,258. In the 2007 package, it was stated that the total cost for one contract was $1,920. However, that was only for 40 hours. If we multiply $1,920 by 6 (to account for what would the cost be for 240 hours, rather than for 40 hours), then the cost for each contract would have been $11,520. We believe that our estimates in 2010 are fair and more realistic than in the previous package.

Finally, the 2007 PRA package did not include the auditing costs. We believe that based on our discussions with NCQA, which is aligned with feedback from the MA contracts that this accounts for most of the cost. The plans must pay for the annual independent auditing assessment which is $7,245,000 for all of the 483 contracts.

(16) Publication / Tabulation Dates

HEDIS® data have been published in beneficiary information products since 1998. 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 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. There is no expiration date.

(18) Certification Statement

There are no exceptions to this certification statement.