Part A: Supporting Statement for Collection of HEDIS® Data

PURPOSE:

The Centers for Medicare & Medicaid Services (CMS) is requesting a renewal of Office of Management and Budget (OMB) number 0938-1028, that expires February 28, 2017, for the currently approved collection of Healthcare Effectiveness Data and Information Set (HEDIS®) data for managed care contracts which include Medicare Advantage Organizations (MAOs) and §1876 cost contracts.. This request for a renewal is supported under the Paperwork Reduction Act and 5 CFR 1320.6. MAOs and §1876 cost contracts 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 MAOs must submit quality performance measures as specified by the Secretary of the Department of Health and Human Services and by CMS. These quality performance measures include HEDIS®. HEDIS® data are used in the Medicare Part C Star Ratings, and HEDIS® data are used in the CMS Quality Bonus Payments to Medicare Advantage plans.

BACKGROUND:

CMS has a responsibility to its Medicare beneficiaries to require that care provided by MAOs and 1876 cost contracts in Part C under contract to CMS is of high quality and conforms to currently accepted standards of medical care. One way of ensuring high quality care in MAOs is publicly reporting quality data indicators. The reporting of quality data is not only beneficial to the public by supporting transparency, but it also contributes to quality improvement in all MAOs.

CMS is committed to assessing the quality of care provided by Medicare Advantage (MA) contracts. CMS began requiring MAOs, formerly called Medicare managed care organizations (MCOs) to collect and report performance measures from HEDIS® beginning in 1998. 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 healthcare 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. All participating contracts pay for the auditing of their HEDIS® data.

All Medicare members covered in the following contracts are included in Medicare HEDIS® reporting. CMS communicates directly with all contracted organizations on HEDIS® reporting requirements. Special Needs Plans (SNPs) are required to report a subset of HEDIS measures, and the SNPs include the dual-eligible, chronic care and institutional benefit packages. The following types of MA contracts (N=515) that are required to report HEDIS® 2017:

- Medicare Advantage-Local CCPs (MA) (N=434)
- Section 1876 cost contracts (N=16)
- Medical Savings Account (MSA) (N=1)
- Private Fee-for-Service (PFFS) (N=7)
- Demonstrations (N=47)
- Regional CCPs (N=10)

HEDIS® 2017 is the latest edition of the measure set, which contains xx measures across x domains of care. Certain quality measures are additionally collected via the Health Outcomes Survey (HOS®) and Consumer Assessment of Healthcare Providers and Systems (CAHPS®) program. The HOS® and CAHPS® surveys have separate OMB PRA packages.

In **Table 1**, we list the required HEDIS® measures in 2017:

Table 1: HEDIS® 2017 Measures for Reporting

HEDIS® 2017 Measures for Reporting: All Organizations Report all Measures except as noted below	
Effectiveness of Care	
ABA	Adult BMI Assessment
BCS	Breast Cancer Screening
COL	Colorectal Cancer Screening
SPR	Use of Spirometry Testing in the Assessment and Diagnosis of Chronic Obstructive Pulmonary Disease (COPD)
PCE	Pharmacotherapy Management of COPD Exacerbation
MMA	Medication Management for People with Asthma
AMR	Asthma Medication Ratio
CBP	Controlling High Blood Pressure
PBH	Persistence of Beta-Blocker Treatment After a Heart Attack[1]
SPC	Statin Therapy for Patients with Cardiovascular Disease[1]
CDC	Comprehensive Diabetes Care[2]
SPD	Statin Therapy for Patients With Diabetes[1]
ART	Disease Modifying Anti-Rheumatic Drug Therapy for Rheumatoid Arthritis

OMW	Osteoporosis Management in Women Who Had a Fracture
AMM	Antidepressant Medication Management
FUH	Follow-Up After Hospitalization for Mental Illness
FUM	Follow-Up After Emergency Department Visit for Mental Illness
FUA	Follow-Up After Emergency Department Visit for Alcohol and Other Drug Dependence
MPM	Annual Monitoring for Patients on Persistent Medications
MRP	Medication Reconciliation Post-Discharge[1]
PSA	Non-Recommended PSA-Based Screening in Older Men
DDE	Potentially Harmful Drug-Disease Interactions in the Elderly
DAE	Use of High-Risk Medications in the Elderly
HOS	Medicare Health Outcomes Survey
FRM	Falls Risk Management (collected in HOS®)
MUI	Management of Urinary Incontinence in Older Adults (collected in HOS®)
OTO	Osteoporosis Testing in Older Women (collected in HOS®)
PAO	Physical Activity in Older Adults (collected in HOS®)
FVO	Flu Vaccinations for Adults Ages 65 and Older (collected in CAHPS®)
MSC	Medical Assistance With Smoking and Tobacco Use Cessation (collected in CAHPS®)
PNU	Pneumococcal Vaccination Status for Older Adults (collected in CAHPS®)
Access/Availability of Care	
AAP	Adults' Access to Preventive/Ambulatory Health Services
IET	Initiation and Engagement of Alcohol and Other Drug Dependence Treatment
Utilization and Risk Adjusted Utilization	
FSP	Frequency of Selected Procedures[1]
AMB	Ambulatory Care
IPU	Inpatient Utilization - General Hospital/Acute Care[1]
IAD	Identification of Alcohol and Other Drug Services[1]
MPT	Mental Health Utilization[1]
ABX	Antibiotic Utilization
HAI	Standardized Healthcare-Associated Infection Ratio
PCR	Plan All-Cause Readmissions[1]
IHU	Inpatient Hospital Utilization[1]
EDU	Emergency Department Utilization[1]
HPC	Hospitalization for Potentially Preventable Complications[1]
Health Plan Descriptive Information	
BCR	Board Certification
ENP	Enrollment by Product Line
EBS	Enrollment by State

LDM	Language Diversity of Membership
RDM	Race/Ethnicity Diversity of Membership
TLM	Total Membership

[1] If they do not have inpatient claims, Section 1876 Cost contracts do not have to report the following inpatient measures: PBH, SPC, MRP, SPD, FSP, IPU, IAD, MPT, IHU, EDU and HPC.

[2] HbA1c control <7% for a selected population is not reported for Medicare contracts.

[3] Section 1876 Cost contracts are not required to report the PCR measure, but may do so voluntarily. If an 1876 Cost contract voluntarily submits audited summary-level PCR data, then the 1876 Cost contract must also have corresponding audited HEDIS PLD data for the PCR measure.

JUSTIFICATION

Statutory and Regulatory Basis

In an effort to promote an active, informed selection among coverage options, the Secretary must provide information to current and potential Medicare beneficiaries about Medicare Advantage organizations, including quality and performance indicators for benefits under the contracts as well as Medicare enrollee satisfaction and information on health outcomes.

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.
(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 preferred 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)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 reports 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

HEDIS® data support CMS' efforts to hold MA contracts 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 quality care 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 MAOs' performances, inform audit strategies, and inform beneficiaries' choices through their display in CMS' consumer-oriented public compare tools and websites. MAOs 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. Measures from HEDIS are included in the Part C Star Ratings and MA Quality Bonus Payments. Additionally, CMS makes health plan level HEDIS® data available to researchers and others as Public Use Files (PUFs) on the CMS website www.cms.hhs.gov.

(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 1998. NCQA estimates that about 95% of MAOs are also collecting some or all of the HEDIS® data for their commercial and/or Medicaid populations. The incremental costs of doing HEDIS® for the Medicare population are small relative to the fixed costs that MAOs have invested in to do it for commercial plans.

(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 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. 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 Federal Register Notice will be posted about August 22, 2016.

(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 because it is collected from health plan administrative data and medical record review. These data are primarily administrative record data and clinical record data.

(12) Burden Estimate (Hours and Wages)

We determined that two type of labor categories were appropriate, that of a Medical Records Review Technologist, and that of a Database Administrator. These are the same labor categories as in the current PRA approval. In addition, the level of effort by these professionals is unchanged from the current PRA approval.

The Medical Records Review Technologist will pull and examine the data, by reviewing the administrative data and the medical records data of the contract members. The Medical Records Review Technologist will pull administrative data from electronic files and will conduct the medical record review. This work will entail approximately 240 hours annually. The total hours for the Medical Records Review Technologist in all contracts will be 240 hours X 515 contracts = 123,000 hours. For the Medical Records Review Technologist position at $37.13 for 240 hours, the cost is $8,911.20 per contract, or $4,598,268 for 515 contracts.

The Database Manager will determine the project parameters for the annual HEDIS® data collection that is needed to be submitted. The Database Manager will need 80 hours to accomplish the work. The total hours for the Database Manager in all contracts will be 80 hours x 515 contracts = 41,200 hours. For the Database Manager position at $49.28 an hour for 80 hours, the cost is $3,942.40 a contract, or $2,030,336 for 515 contracts.

The total annual cost burden to the 515 contracts is $4,598,268+$2,030,336=$6,619,604.

Table 2: Annual Cost Burden to 515 MA Contracts for HEDIS Data Collection

	Medical Record Reviewer	Database Manager	Total For Both Categories
Hours	123,000	41,200	164,200 hours
Costs	$4,598,268	$2,030,336	$6,619,604

(13) Capital Costs

There are no capital costs.

(14) Cost to Federal Government

The Federal contract cost for HEDIS® data collection to the federal contractor(s) is about $400,000 annually. In addition to the federal contractor costs, CMS funds one GS-14 to be the COR for the HEDIS® data collection, and the CMS COR's work associated with the HEDIS® contract is approximately 20% of her 40-hour weekly work schedule.

(15) Changes to Burden

There are no changes.

(16) Publication /Tabulation Dates

HEDIS® data have been published in beneficiary information products since 1998 and have consistently been contained in more CMS information products about quality assurance over time. 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. This information is available through the beneficiary website in an enhanced comparison tool called Medicare Plan Finder. CMS makes health plan-level HEDIS® data freely available to researchers and others in Public Use Files on the CMS website (www.cms.hhs.gov).

(17) Expiration Date

HEDIS® data collection is an ongoing endeavor. There is no expiration date.

(18) Certification Statement

There are no exceptions to this certification statement.