Supporting Statement for Paperwork Reduction Act Submissions:
Part C Medicare Advantage Reporting Requirements and
Supporting Regulations in 42 CFR §422.516 (a)

A. Background

The Centers for Medicare & Medicaid Services (CMS) has received many inquiries about operations, costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to the performance of Medicare Advantage Organizations (MAOs) under Medicare Part C. To date, CMS has not been able to address many of these inquiries because of an absence of data. CMS needs to initiate data collection in these and other areas that have been the subject of recent inquiries by both governmental and private groups in order to improve its performance monitoring of MAOs. For example, on February 27, 2008, the CMS Acting Administrator testified before the House Ways and Means Subcommittee regarding the value of Medicare Advantage (MA) relative to traditional fee-for-service Medicare. His statement can be found at http://www.hhs.gov/asl/testify/2008/02/t20080227a.html. On that occasion and others, Congress has requested data regarding the utilization of MA benefits by plan enrollees. However, CMS has not collected utilization and expenditure data to enable it to accommodate Congress' request nor to conduct its own analyses of the use of rebate dollars.

CMS has authority to establish reporting requirements for MAOs as described in 42CFR §422.516 (a). Pursuant to that authority, each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the cost of its operations, patterns of service utilization, availability, accessibility, and acceptability of its services, developments in the health status of its enrollees, and other matters that CMS may require. Additional regulatory support for Medicare Part C measures is also found in final rule "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Program" (CMS 4131-F) and the interim final rule 4138-IFC issued September 18, 2008 and 4138-IFC2 issued November 10, 2008

By way of the "2009 Call Letter," CMS informed MAOs that new Part C reporting requirements will be established (http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CallLetter.pdf). CMS provided trade associations and all MA plans with an overview of the proposed part C reporting requirements via the Part C and D user group on March 17, 2008. Updates were provided on July 9, 2008 and October 15, 2008. CMS is requesting a three-year Office of Management and Budget (OMB) approval of the reporting of these twelve measures from MAOs. MAOs will be required to collect these data beginning on January 1, 2009. Reporting will vary depending on the measure; some measures will be reported annually, while others will be reported quarterly or semi-annually. Attachment I (Part C Reporting Overview) contains the reporting periods for all the measures as well as the plan types that will be required to report.

CMS included cost plans in its reporting requirements outlined in the Federal Register notice on

June 26, 2008. After careful consideration, CMS has determined that because of the unique operation of cost plans, CMS will not require cost plans to comply with the following reporting requirements: benefit utilization; procedure frequency; and serious reportable adverse events. However, CMS has determined that it is essential that all beneficiaries understand rules and requirements of the Medicare plans which they are being invited to join. Prospective enrollees in cost plans should be furnished accurate information by qualified sales people, consistent with CMS' expectation for prospective enrollees in other plan types. Thus, we are requiring reporting on certain measures that we believe are critical in monitoring cost plans. We believe compliance with the reporting requirements identified below is within CMS's oversight authority to ensure cost plan compliance with marketing activities. Additionally, we believe that section 1876(i)(1)(D) of the Act, which requires cost plans to "provide the Secretary with such information as the Secretary may find necessary and appropriate" and §417.126(a)(6) and §417.486(a) of the CFR permit us to require cost plans to report to CMS the data identified below.

The reporting requirements for cost plans are as follows:

- Provider network adequacy
- Grievances
- Organization determinations/reconsiderations
- Employer group plan sponsors
- Agent training and testing
- Agent compensation structure
- Plan oversight of agents

The other significant revisions to Part C reporting requirements are due to statutory and regulatory revisions that have occurred after June 26, 2008. Besides the 12 measures reported in the June 26, 2008 Federal Register Notice, in the 30-day notice, an additional measure was added: Special Needs Plans (SNPs) Care Management. This measure was added because of a statutory change; that is Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which requires all SNPs to have an evidenced-based model of care with appropriate networks of providers and specialists. In addition, several measures , including agent compensation structure, training and testing of agents, and plan oversight of agents, were revised as a result of MIPPA and the finalization of our regulation entitled, Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Program" (CMS 4131-F)

All thirteen measures included in this package are subject to audit. The approval of the collection of these measures will enable CMS to meet requests for information about the Part C program from Congress and federal agencies, to monitor and measure compliance of MAOs with federal regulations, to ensure that Medicare beneficiaries have access to information about their health plans, and to ensure that beneficiaries are provided with care that is of high quality and is safe, effective, and timely. In addition to the narrative description of these measures which follows, a synopsis of these measures is contained in Attachment II: Part C Reporting Requirements Detail Chart.

The following data elements in the measures listed below are considered proprietary and not

subject to public disclosure under provisions of the Freedom of Information Act (FOIA):

- Per service costs in the benefit utilization measure (Benefit Utilization)
- Employer DBA and Legal Name, Employer Address, Employer Tax Identification Numbers (Employer Group Sponsors)
- Total agent compensation related to sales (Agent Compensation Structure)

1. Benefit Utilization

Unlike original Medicare, MAOs are currently not required to submit claims-like information on encounters for either Medicare covered or uncovered services provided. However, MAOs apply rebates from Medicare to "buy down" the cost of both. Some examples of added, non-covered, or supplemental services include: vision exams and eye glasses, dental care, smoking cessation programs, and fitness classes. MAOs can also buy down cost sharing for Part B services or eliminate coverage limits for benefits such as acute inpatient hospital care. Currently, MAOs project the use of rebate dollars as part of their annual bid submission. This data collection effort will require that the MAOs provide information on how services and rebate dollars were actually used. CMS can then use these data to compare rebate amounts with supplemental services and increased cost sharing to determine how the rebate dollars are being used.

In addition, Congress has requested data regarding the utilization of MA plan benefits by MA enrollees. To date, CMS has not collected data to enable a response to Congress' request nor to conduct its own analyses of the use of MA rebate dollars. The eligible population for the benefit utilization measure is all beneficiaries enrolled in a plan benefit package (PBP) for a minimum of one month during the year. For each service category, the proposed data elements for the eligible population are (please refer to Attachments III and IV for additional information):

A. Member months of enrollees with the benefit
B. Number of Utilizers
C. Utilization type
D. Total Utilization
E. Total Plan Reimbursement
F. Total Member Cost Sharing
G. Allowed Cost
H. Total Medicare Covered (Allowed Cost)
I. Supplemental Benefits (Allowed Cost)
J. Medicare Actuarial Equivalent (Cost Sharing):
K. Supplemental Benefits (Cost Sharing)
L. Total Supplemental Benefits
M. Total Enrollees

N. Total Member Months

O. Total Premiums Collected

P. Total CMS Part A & Part B Rebates Collected

Q. Total Reserve for Outstanding Claims

The data will be reported on an incurred basis, including claims paid during the calendar year and those paid during the first six months of the following year (June 30). Added to these paid amounts will be the plan's estimate of claims that were incurred during the calendar year, but yet to be paid as of the following June 30 ("claim reserves"). The claim reserves will be included for each service category, and the total claim reserve will be reflected in the summary section of the report. Only rebates applied to Part A/B services should be included in rebate reporting.

Attachment III entitled "Medicare Advantage Medical Utilization and Expenditure Experience" contains information on the specific service categories that will be reported.

Attachment IV contains a mapping of the MA PBP to medical utilization and expenditure experience. This attachment provides the linkage of the service categories on the MA medical utilization and expenditure experience exhibit to the MA PBP categories.

Under the proposed rule entitled "Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009" (CMS-1390-P), appearing in the Federal Register (Vol. 73, No. 84 / Wednesday, April 30, 2008 / Proposed Rule), CMS would have the authority to require MAOs to submit encounter data for each item and service provided to the MA enrollee. However, there is no schedule of collection of encounter data contained in the proposed rule. We expect that there will be one year of overlap in the collection of encounter data and Part C reporting of benefit utilization. Even then, information on how rebates are used by MAOs is not available via encounter data.

Reporting for this measure will be at the level of the plan benefit package (PBP). Procedure codes are based on the PBP and Bid Pricing Tool (BPT) requirements.

Regulatory support for these measures is found in 42 CFR, Subpart K 422.516, which requires that each MA plan have an effective procedure to develop, compile, evaluate, and report to CMS statistics and other information on patterns of utilization of its services.

2. Procedure Frequency

The data elements for these measures are the number of enrollees with:

A. Cardiac Catheterization
B. Open coronary angioplasty
C. PTCA or Coronary Atherectomy with CABG
D. PTCA or Coronary Atherectomy with insertion of drug-eluting coronary artery stent (s)
E. PTCA or Coronary Atherectomy with insertion of non-drug-eluting coronary artery stent (s)
F. PTCA or Coronary Atherectomy without insertion of Coronary Artery Stent
G. Joint Replacements (Hip/Knee)
H. Transplants (Heart/Heart/Lung ,Kidney Liver, Lung, Pancreas, Kidney, Bone Marrow)
I. Gastric Bypass
J. Cancer Surgeries (Lung, Large Intestine, Breast, Prostate)

Collection frequency is once on an annual basis. Current HEDIS measures that are also in this list include: cardiac catheterization, CABG, prostatectomy, total hip replacement, total knee replacement, partial excision of large intestine, mastectomy, and lumpectomy.
Some MAOs and Private Fee-for-Service (PFFS) plans are already reporting a subset of these measures via HEDIS® and will continue to use HEDIS® to report them. These MAOs will not be required to report separately on the measures that they already report via HEDIS®. While PFFS plans are exempt from HEDIS® reporting, they will be required to report all of these measures, whether or not the measures are part of the HEDIS® set. CMS is supplying the procedure (and diagnosis codes for the cancer surgeries) in Attachment V. Refer to Attachment I for the plan types required to report "procedure frequency" measures.

Regulatory support for these measures is found in 42 CFR Subpart K 422.516 requiring that each MA must have an effective procedure to develop, compile, evaluate, and report to CMS statistics and other information on availability, accessibility, and acceptability of its services.

3. Serious Reportable Adverse Events

This set of measures involves both serious reportable adverse events and hospital-acquired conditions. Serious adverse events, usually preventable, result in harm to thousands of patients annually. Reliable and valid reporting about the occurrence of these events, which also contribute to the high cost of medical care, is necessary so that the causes of these events can be identified and processes of care improved, leading to their minimization if not elimination.

The National Quality Forum (NQF) has developed a list of serious reportable adverse events (http://www.ahrq.gov/downloads/pub/advances/vol4/Kizer2.doc.) These include surgeries on the wrong body part, surgeries on the wrong patient, wrong surgical procedures on a patient, surgery with a foreign object left in the patient after surgery, and surgery with post-operative death in a normal health patient.

Section 5001(c) of the Deficit Reduction Act of 2005 requires the Secretary to identify conditions that are: (a) high cost or high volume or both, (b) result in the assignment of a case to a diagnosis related group (DRG) that has a higher payment when present as a secondary diagnosis, and (c) could reasonably have been prevented through the application of evidence-based guidelines. Consequently, CMS presented eight conditions that were selected for the Hospital Acquired Condition (HAC) payment provision on August 1, 2007, in the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2008 Final Rule. The eight selected conditions include: foreign object retained after surgery, air embolism, blood incompatibility, Stage III and IV pressure ulcers, fractures, dislocations, intracranial injuries, crushing injuries, burns, catheter-associated urinary tract infection (UTI), vascular catheter-associated infection, and surgical site infection-Mediastinitis after Coronary Artery Bypass Graft (CABG).

On April 14, 2008, CMS posted the IPPS FY 2009 Proposed Rule which presents additional candidate conditions. Payment implications will begin October 1, 2008, for the first eight conditions and any of the candidate conditions that are selected in the IPPS FY 2009 final rule. Both the 2008 and 2009 IPPS rule pertain to original Medicare. They do not, however, pertain to Part C Medicare. In order to ensure MAOs are subject to the same requirements regarding adverse events as original Medicare, CMS needs to collect these data from MAOs.

The data elements are:

Never Events

A. # surgeries on wrong body part
B. # surgeries on wrong patient
C. # wrong surgical procedures on a patient
D. # surgeries with foreign object left in patient after surgery
E. # surgeries with post-operative death in normal health patient
F. # total surgeries

Hospital Acquired Conditions (number of the following)

G. Air Embolism
H. Blood Incompatibility
I. Stage III & IV Pressure Ulcers
J. Falls and Trauma Fractures, Dislocations, Intracranial Injuries, Crushing Injuries, Burns
K. Catheter-Associated UTI
L. Vascular Catheter-Associated Infection
M. SSI (Mediastinitis) after CABG
N. SSI after certain Orthopedic Procedures
O. SSI following Bariatric Surgery for Obesity
P. DVT and pulmonary embolism following certain orthopedic procedures
Q. Manifestations of Poor Glycemic Control

Collection frequency is once per year.

Regulatory support for these measures is found in 42 CFR Subpart E 422.516, which requires that each MAO have an effective procedure to develop, compile, evaluate, and report to CMS statistics and other information to the extent practical, including developments in the health status of its enrollees.

4. Provider Network Adequacy

MAO applicants must demonstrate network adequacy when they apply to the MA program. However, CMS does not presently have a mechanism for assuring continued network adequacy in out years. Yet, CMS is responsible for monitoring MAOs to ensure sufficient beneficiary access. Provider access and continuity remains a critical issue to member satisfaction and utilization of appropriate services. All MAOs that coordinate care will be required to report this measure, which will include the following data elements:

A) Number of primary care physicians (PCPs) in network on first day of reporting period by type of PCP
B) Number of PCPs in network continuously through reporting period by type of PCP
C) Number of PCPs added to network during reporting period by type of PCP
D) Number of PCPs in network on last day of reporting period by type of PCP
E Number of PCPs accepting new patients at start of reporting period by type of PCP
F) Number of PCPs accepting new patients at end of reporting period by type of PCP
G) Number of specialists in network on first day of reporting period by type of specialist/facility
H) Number of specialists in network continuously through reporting period by type of specialist/facility
I) Number of specialists added during reporting period by type of specialist/facility
J) Number of specialists in network on last day of reporting period by type of specialist/facility

CMS permits MAOs to count as Primary Care Providers (PCPs) physicians that practice general medicine, family medicine, internal medicine, obstetricians, pediatricians, and state licensed nurse practitioners. This is consistent with CMS' longstanding policy for determining network adequacy for new applicants. Gynecologists and Geriatricians may be considered as PCPs for CMS' reporting requirements as long as providing primary care services are consistent with their provider contracts with the MAO. The ten other provider and facility types are: (1) Hospitals, (2) Home Health Agencies (Medicare Certified), (3) Cardiologist, (4) Oncologist, (5) Pulmonologist, (6) Endocrinologist , (7) Skilled Nursing Facilities, (8) Rheumatologist, (9) Ophthalmologist, and 10 (Urologist). This will not increase reporting burden since the provider/facility grouping are now consistent with HSD definitions.

The reporting frequency will be once on an annual basis.

Regulatory support for the collection of these data elements is found in 42 CFR Subpart E 422.204, which requires that an MA organization have written policies and procedures for the selection and evaluation of providers. These policies must conform to the credential and recredentialing requirements set forth in paragraph (b) of this section and with the

antidiscrimination provisions set forth in 422.205. In addition, 422.112 sets forth requirements for access to services.

5. Grievances

A grievance is any complaint or dispute, other than one involving an organization determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of an MA organization, regardless of whether remedial action is requested. Grievances are complaints or disputes that are expressed directly to the plan rather than to 1-800 MEDICARE or to the CMS regional or central office. CMS currently collects grievances related to Part D but needs Part C grievance data to determine if there are issues that are troubling to enrollees and may adversely affect their privacy, access to care, satisfaction with their plan, and the quality of care they are receiving.

MAOs are required to track and maintain records on all grievances received both orally and in writing. The data elements are number of grievances by category of grievance as follows :

A) fraud/abuse
B) enrollment/disenrollment access/benefit package
C) marketing
D) confidentiality/privacy
E) quality of care
F) grievances related to expedited requests
G) other grievances not fitting under any of the above categories

The reporting frequency will be four times per year.

Regulatory support for the measure is found in 42 CFR Subpart M 422.564 which requires that the MA organization have an established process to track and maintain records on all grievances received both orally and in writing.

6. Organization Determinations/Reconsiderations

CMS currently has data on the number of appeals processed by the Independent Review Entity (IRE) and the outcome of the appeals. However, CMS cannot calculate an appeal rate, because it does not have data on all MAO organization determinations and reconsiderations. Again, CMS collects these data on Part D but does not collect these measures for MA.

The data elements for organization determinations are:
A) determinations that are fully favorable to enrollee
B) determinations that are partially favorable to enrollee
C) determinations that are adverse to enrollee
D) total determinations (A+B+C)

The data elements for reconsiderations are:

A) reconsiderations fully favorable to enrollee
B) reconsiderations partially favorable to enrollee
C) reconsiderations adverse to enrollee
D) total reconsiderations issued (A+B+C)

The reporting frequency will be four times per year.

Regulatory support for these measures is found in 42 CFR Subpart M 422.566 – 422.576 that states that each MAO must have a procedure for making timely organization determinations regarding the benefits an enrollee is entitled to receive under the MA plan, including basic benefits and mandatory and optional supplemental benefits, and the amount, if any, that the enrollee is required to pay for a health service. Additional support is found in 42 CFR Subpart M 422.578 and 42 CFR Subpart K 422.516 (a) (6) requiring that each MAO have an effective procedure to develop, compile, evaluate and report to CMS statistics and other information on other matters that CMS may require.

7. Employer Group Plan Sponsors

CMS does not collect any information on the employer and union group plan sponsors that contract with MAOs to offer benefits using either individual or "800 series" Medicare plans, and CMS does not know which employer plans are purchasing individual plans for their employee group. This information is needed to monitor these plans effectively and to ensure that our statutory waiver authority is being used in accordance with our statutory mandates.

CMS has statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored plans offered by Medicare Advantage Organizations (MAOs), set forth in Section 1857(i) of the Social Security Act. Under the above-referenced statutory authority, MAOs are permitted to utilize these waivers to contract with employer and union group sponsors to facilitate the enrollment of their Medicare-eligible retirees into MA plans. (Please note that in addition to these "indirect contract" arrangements, CMS also has separate statutory authority to directly contract with employers and union group plan sponsors to offer a Medicare benefit to their retirees). When exercising our discretion to grant these statutory waivers or modifications to MAOs offering these plans, these waivers and/or modifications are conditioned upon the MAO meeting a set of conditions and complying with certain requirements, which may include these kinds of reporting requirements.

In addition to being a condition of receiving these waivers, the information requested is necessary for CMS to fulfill its affirmative oversight obligation to ensure MAOs and the employer groups that contract with the MAOs are properly utilizing these waivers and modifications and that CMS' statutory waiver authority is being implemented in accordance with the requirements of the Section 1857(i) of the Act.

The Tax Identification Number (TIN) is the standard unique employer identifier. The Medicare program uses the TIN to identify employers and businesses in other areas of the program. For

example, MAOs and other insurers are required to report TIN information in order to comply with the mandatory Medicare Secondary Payer insurer reporting requirements of Section 111 of the Medicare, Medicaid, and SCHIP Extensions Act of 2007 (Public Law 110-173). Thus, some of these same entities (MAOs and employer/union sponsors) affected by our reporting requirements will similarly be required by law to collect and report TIN information to CMS for Medicare secondary payment purposes.

Additionally, while we understand that it can be a challenge for the MAOs to collect TINs from the employer/union sponsors, as outlined above, this information is necessary to ensure that our statutory waiver authority is being properly implemented. If employer/union sponsors are unable or unwilling to provide TINs or other required information necessary to ensure our waiver authority is being properly implemented, MAOs should notify these sponsors that they will be unable to utilize the waivers available to employer/union group health plans to take advantage of these kinds of unique Medicare options and should work with them to explore other Medicare options for their retirees.

The data elements that are required are:
A) Employer Legal Name
B) Employer DBA Name
C) Employer Federal Tax ID
D) Employer Address
E) Type of Group Sponsor (employer, union, trustees of a fund)
F) Organization Type
G) Type of Contract (insured, ASO, other)
H) Employer Plan Year Start Date
I) Current/Anticipated enrollment

All individual MA plans and "800 series" MA Plans offered to employer groups are required to report these data (CCP, PFFS, 1876 cost, Demo, MSA). Reporting will be at the PBP level.

The reporting frequency is twice per year.

Regulatory support for data collection is found in 42 CFR, Subpart K 422.516, which requires each MA to have an effective procedure to develop, compile, evaluate, and report to CMS statistics and other information on other matters that CMS may require. Statutory employer group waiver authority is found in Sections 1857(i) (MAOs) and Section 1860D-22(b) (PDPs) of the Social Security Act.

8. Plan Enrollment Verification Calls

CMS has received many inquiries about operations, costs, availability of services, beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to the performance of Medicare Advantage Organizations (MAOs) under Part C Medicare. In 2007,

CMS received a number of complaints from beneficiaries who claimed they either did not enroll in a PFFS plan initially or they did so without receiving a follow-up verification call or letter as required by guidance memorandum. To date, CMS has not been able to address many of these inquiries because of an absence of data. CMS will measure whether PFFS plans are completing enrollment verification activities for their new members as required. CMS will also identify which PFFS plans have the highest proportion of prospective members opting not to enroll in a PFFS plan during the enrollment verification process—suggesting which PFFS plans are at risk for poor marketing practices.

The data elements are:
A) the number of times the PFFS plan reaches the prospective enrollee with the first call of up to three required attempts in reporting period
B) Number of follow-up educational letters sent in reporting period
C) Number of enrollments in reporting period

These data will be reported only in 2009 for PPFS plans. New plan types are required to conduct enrollment verification. They will report at the PBP level.

Excluded from the above data elements and calculations are enrollments via the Medicare website or through 1-800-MEDICARE.

The reporting frequency will be once per year,

The regulatory support for the measure is found in 42 CFR Subpart B 422.50 - Eligibility to elect an MA Plan.

9. Provider Payment Dispute Resolution Process

Claims payment accuracy and timeliness are among the most common complaints against PFFS plans. CMS is presently without a mechanism for measuring PFFS performance in this area, and has not been able to empirically respond to numerous inquiries on the scope of this issue. PFFS plans must have a provider payment dispute resolution in place to consider provider allegations of improper payment in a timely and reasonable manner; CMS presently has no data on these processes; these measures will, for the first time, give CMS information on which to monitor plans, to report to Congress and to report to other stakeholders on the extent to which PFFS plans are failing to accurately resolve payment disputes in a timely manner.

The data elements are:
A) Number of provider payment denials overturned in favor of provider on appeal.
B) Number of provider payment appeals
C) Number of provider payment appeals resolved in greater than 60 days

These data will be reported only for PPFS plans. Reporting will be at the PBP level.

The data will be reported once annually.

Regulatory support for the measures is found in CFR 42, Subpart M 422.608 Medicare Appeals Council Review; CMS Model PFFS Terms and Conditions that stipulates that PFFS MAOs must have a provider dispute resolution process in place.

10. Agent Compensation Structure

CMS has received a number of complaints regarding the structures of agent compensation that often leads to enrollee "churning" where enrollees are moved from one plan to another for reasons that are in the agent's financial interest, not necessarily the beneficiary's best interest or "steering" where, beneficiaries are pushed to plans that are the most profitable for the agent but not necessarily the most beneficial to the enrollee.
On September 15, 2008, CMS released guidance to help the industry implement the new Medicare regulations, CMS 4131-F and CMS 4138-IFC. The guidance addressed important changes for Medicare Advantage (MA) plans, Medicare Prescription Drug Plans (PDP) and Cost-based plans. Subsequently, we conducted briefings and answered questions related to implementation of the rules. CMS received a great deal of feedback about agent/broker compensation. As a result, on November 10, 2008, CMS issued a new interim final regulation with comments (CMS 4138-IFC2) addressing agent/broker compensation. These requirements will assist CMS in monitoring compliance with the new regulations both in CY 2009 and subsequent years. CMS is requesting data on licensed independent agents. The data pertain to both new enrollees and retained enrollees.

For the CY 2009 and subsequent reporting periods, MAOs and Cost contractors will report the following data elements:

A) Number of licensed independent agents for reporting period who made a Part C or Part D or Cost plan sale.

B) Number of beneficiaries making an enrollment change in reporting period for which an agent was involved as defined above.

C) Number of beneficiaries retained in reporting period for which an agent was involved as defined above.

D) Total licensed independent agent compensation for beneficiaries making an enrollment change in reporting period for which an agent was involved.

E) Number of licensed independent agents who received compensation for retained enrollees

F) Total licensed independent agent compensation for beneficiaries retained from previous reporting period for which an agent was involved as defined above.

CY 2009 and Subsequent Year Data Element Representation

Licensed Independent Agents
Number of agents in reporting period
Number new enrollees for which agent was involved in reporting period
Total compensation related to volume of sales involving new enrollees in reporting period
Number of beneficiaries retained in reporting period
Number of agents who received compensation for retained enrollees
Total compensation related to retained enrollees in reporting period

The data will be reported once annually.

A similar requirement for prescription drug plans (PDPs) will be added in the 2010 Part D reporting revisions.

11. Agent Training and Testing`

CMS has received complaints from MA enrollees that agents have insufficient knowledge of Medicare and health plan benefits of MA plans. Frequently, agents are said to be uninformed of specific requirements of PFFS plans or provider requirements. Agents must be trained in order to accurately represent plan benefits and the MA program and Cost program to prospective enrollees. Testing is an accepted indicator of training success. CMS will use these data to determine if all agents completed training and testing and if the minimum passing score should be raised. CMS is requesting data on licensed marketing representatives who are employees of the MAO or Cost contractor and licensed independent agents. Data will be reported separately for these two agent types and program types.

The data elements are:
A) Total number of agents in contract year
B) Number of agents in contract year that completed training successfully
C) Number of agents in contract year with a passing score of 85% or above on first testing
D) Average scores of agents in contract year with a passing score of 85% or above on first testing
E) Number of agents taking second test
F) Number of agents in contract year with a passing score of 85% or above on second testing
G) Average scores of agents in contract year with a passing score of 85% or above on second testing
H) Number of agents in contract year taking test 3 or more times

Reporting will pertain only to agents who are actively marketing on behalf of the MAO.

The data will be reported once annually.

Regulatory support for the measures is found in 422.2274(b) and 423.2274(b) of CMS 4131-IFC. Under the rule, MA organizations would be required to train all agents selling Medicare products on Medicare rules, regulations and compliance-related information. Also, in 42 CFR 422.2274(c) and 423.2274(c), agents selling Medicare products would be required to pass written or electronic tests on Medicare rules, regulations and information on the plan products they intend to sell. A requirement for PDPs the same as this one will be added in the 2010 Part D reporting revisions.

12. Plan Oversight of Agents

MAOs and Cost contractors are responsible for monitoring the conduct of agents. Because states oversee the licensing of agents, plans should be working closely with states on agent conduct issues. CMS will monitor agent complaints to determine if organizations are investigating identified complaints and imposing disciplinary actions as well as reporting poor conduct to the state. CMS is requesting data on licensed marketing representatives who are employees of the MAO or Cost contractor and licensed independent agents. Data will be reported separately for these two agent types.

Data elements are as follows:
A) Number of agents
B) Number of agents investigated based on complaints
C) Number of agents receiving disciplinary actions based on complaints
D) Number of complaints reported to State by MAO or Cost contractor
E) Number of agents whose selling privileges were revoked by the plan based on conduct or discipline
F) Number of agent-assisted enrollments

Reportable revocations of selling privileges are those that stem specifically from marketing conduct. Disciplinary action is defined as “all forms of corrective and disciplinary action (i.e., agents who were alerted to a compliance infraction, directed to retake training certifications, etc.).”

The data will be reported quarterly.

Regulatory support for the measures is found in 42 CFR, Subpart K 422.516(a). In 422.2274(e) and 423.2274(e) of final rule “Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Program” (CMS 4131-F), and MA organizations would be required to comply with State requests for information about the performance of licensed agents or brokers as part of a state investigation into the individual’s conduct. A similar requirement for prescription drug plans (PDPs) will be included in the 2010 Part D reporting revisions.

13. Special Needs Plans (SNPs) Care Management

This measure was added since the last notice on June 26, 2008, because of Section 164 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) that requires all SNPs to have an evidenced-based model of care with appropriate networks of providers and specialists. The plans would be required to: conduct an initial assessment and annual reassessment of each enrollee's physical, psychological, and functional needs, develop a plan that identifies goals and objectives, measurable outcomes, and specific services and benefits to be provided, and use an interdisciplinary team in the care management.

Special needs individuals were identified by Congress as: 1) institutionalized; 2) dually eligible; and/or 3) individuals with severe or disabling chronic conditions. The initial assessment of enrollees' physical, psychological, and functional needs as well as an annual reassessment of these needs is a crucial element to effective care management

The data elements will be:

A. # new enrollees
B. # enrollees eligible for an annual reassessment
C. # initial assessments performed on new enrollees during reporting period
D. # annual reassessments performed on enrollees eligible for a reassessment

Data collection will be on an annual basis. Data are reported at the PBP level. Refer to Attachment II for more reporting details. This reporting will occur beginning January 1, 2009.

B. Justification

1. Need and Legal Basis

We have provided the legal basis for each of the data elements.
Generally, in accordance with 42 CFR § 422.516 (a), each MA organization under Part C Medicare is required to have an effective procedure to provide statistics indicating:

1) The cost of its operations.
2) The patterns of utilization of its services.
3) The availability, accessibility, and acceptability of its services.
4) To the extent practical, developments in the health status of its enrollees.
5) Other matters that CMS may require.

2. Information Users

Data collected via MA organization Part C Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the benefits provided by MA plans to enrollees. Data will be validated, analyzed, and utilized for trend reporting by CMS. If outliers or other data anomalies are detected, the CMS division with primary responsibility for overseeing this reporting requirement will work in collaboration with CMS components for follow-up and resolution.

3. Use of Information Technology

MA organizations will utilize the Health Plan Management System (HPMS) to submit or enter data for 100% of the data elements listed within these reporting requirements. The reporting time periods vary for each section of the reporting requirements, on a quarterly, semi-annual or yearly basis. HPMS is the current conduit by which MA organizations submit data to CMS; for example, application materials, bids, and formularies (if offering Medicare Part D). CMS and its subcontractors, in turn, communicate to MA organizations regarding this information, including approval and denial notices and other related announcements through HPMS. HPMS, therefore, is already a familiar tool to MA organizations. If organizations are already reporting data elements through HEDIS®, they will be exempt from reporting identical information under this PRA package. Additionally, as access to HPMS must be granted to each user, and is protected by individual login and password, electronic signatures are unnecessary.

4. Duplication of Efforts

This collection does not contain duplication of similar information.

5. Small Businesses

There are no small businesses involved.

6. Less Frequent Collection

In an effort to reduce the burden for MA organizations, each reporting requirement section varies its reporting timeline to capture data as frequently as necessary without increasing undue burden for MA organizations. Nine reporting requirements involve once annual reporting; one involves twice annual reporting (semi-annual), and three involve four times (quarterly) annual reporting. Less frequent collection of the reporting requirement data from MA organizations would severely limit CMS' ability to perform accurate and timely oversight, monitoring, compliance and auditing activities around the Part C MA benefits.

7. Special Circumstances

    - As mandated by 42CFR §422.504 (d), MA organizations must agree to maintain for 10 years books, records, documents and other evidence of accounting procedures and practices.
    - CMS could potentially require clarification around submitted data, and therefore CMS may need to contact MA organizations within 60 days of data submission.

8. Federal Register/Outside Consultation

    The 2009 Part C reporting requirement document was posted in the Federal Registry for a 60-day comment period on June 27, 2008. The Federal Register notice for a 30-day comment period was published on October 3, 2008. CMS staff has reviewed all received comments and questions and revised the document as appropriate. The revised document will be forwarded to the Office of the DHHS Secretary for submission to OMB.

9. Payments/Gifts to Respondents

    There are no payments/gifts to respondents associated with this information collection request.

10. Confidentiality

    CMS will adhere to all statutes, regulations, and agency policies. CMS will not be requesting any beneficiary identification information. Social security numbers will not be collected.

11. Sensitive Questions

    CMS will adhere to all statutes, regulations, and agency policies.

12. Burden Estimates (Hours & Wages)

    Many of the data elements required to support the new Part C Reporting Requirements are already available to MA organizations. Anticipated staff performing these data collection would be data analysts, and/or IT analysts. An average competitive hourly rate (including wages, benefits and overhead) of $54.63 was used to calculate estimated costs.

    Estimated number of respondents for MAOs = 718 (The number of respondents is based on the number of local and regional coordinated care plan contracts, Medicaid Advantage Demonstrations for CY2008 reported in HPMS, 1876 cost plans, MSA plans, and PFFS plans.) Frequency of data submission will be annually for nine measures, quarterly for three measures, and semi-annually for one measure. The 2009 burden estimates are as follows:

2009 Estimates:

Overall estimated burden:

Total annual hours = 382,592
Average cost/Hr. for IT specialists and Data Analysts = $54.63
Total costs = Total annual hours x $54.63 = 382,592 x $54.63 = $20,899,088

Estimated burden per respondent:

Total number of respondents = 718
Average annual hours per respondent = total annual hours / total respondents = 544.2 hours
Average cost per respondent = total costs / number of respondents = $20,899,088/718 = $29,728

2010 and Later Year Estimates (not adjusted for inflation):

Overall estimated burden:

Total annual hours = 286,944
Average cost/Hr. for IT specialists and Data Analysts = $54.63
Total costs = Total annual hours x $54.63 = 286,944 x $54.63 = $15,674,316

Estimated burden per respondent:

Total number of respondents = 718
Average annual hours per respondent = total annual hours / total respondents = 408.2 hours
Average cost per respondent = total costs / number of respondents = $15,674,316/718 = $22,296

Estimated start up costs in 2009:

Estimated total start up costs (all MAOs combined) = Year 2009 total estimated cost – Year 2010 total estimated cost = $20, 899,088 - $15, 674,316 = $ $5,224,772

Estimated total start up cost per MA organization = total estimated start up costs / number of organizations = $5,224,772 / 718 = $7,276.84.

The burden for Section 8 – 42 CFR 422.516 (a)(5) is currently approved under OMB# 0938-0469 (CMS-906) : “The Fiscal Soundness Reporting Requirements” Paperwork Reporting Act package. Therefore, it is not included here.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

    It will cost an estimated $300,000 to develop the Part C reporting requirements module in the Health Plan Management System (HPMS), the CMS health plan reporting tool...

15. Changes to Burden

    There is no change in burden from the 30-day notice issued October 3, 2008.

16. Publication/Tabulation Dates

    Collection of these data will commence in January 1, 2009. The collection of these data from MA organizations will continue indefinitely.

17. Expiration Date

    This collection does not lend itself to displaying an expiration date.

18. Certification Statement

    There are no exceptions.

C. Collections of Information Employing Statistical Methods

MAOs will only be reporting data elements and cost plans will only be reporting data elements. Therefore, this information collection does not employ any statistical analyses or sampling procedures to be conducted by the reporting organizations.