Supporting Statement for Paperwork Reduction Act Submission:
Part C Medicare Advantage Reporting Requirements and
Supporting Regulations in 42 CFR §422.516 (a)
CMS-10261, OCN 0938-1054

Response to December 20, 2011, Terms of Clearance

CMS continues to agree to include the technical specifications document in the ICR package and to make it available to the public during the public comment periods. CMS also understands that all burden-impacting changes--even technical changes like procedure and diagnosis codes that are revised annually--are subject to the PRA and require an opportunity for public comment before they are implemented. This includes changes that would require respondents to change their workflow processes or computer programs in order to accommodate those changes.

Background

The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42CFR §422.516 (a). It is noted that 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 following:

(1) The cost of its operations.
(2) The patterns of service utilization.
(3) The availability, accessibility, and acceptability of its services.
(4) To the extent practical, developments in the health status of its enrollees.
(5) Information demonstrating that the MAO has a fiscally sound operation
(6) Other matters that CMS may require.

CMS also has oversight authority over cost plans which includes establishment of reporting requirements.

CMS initiated new Part C reporting requirements with the Office of Management and Budget (OMB) approval of the "Information Collection Request" (ICR) under the Paperwork Reduction Act of 1995 (PRA) in December 2008 (OMB # 0938-New; CMS-10261). National PACE plans and 1833 cost plans are excluded from reporting all the new Part C Reporting Requirements reporting sections. The initial ICR involved thirteen "measures" now termed "reporting sections." Four of these thirteen sections have been suspended from reporting because the information is available elsewhere: Reporting Section # 1 *Benefit Utilization*; Reporting Section #3 *Provider Network Adequacy*; Reporting Section #10 *Agent Compensation Structure* and; Reporting Section #11 *Agent Training and Testing*. One new reporting section was added beginning 2012: Enrollment and Disenrollment. (The ICF Reference number is 201105-0938-008. The OMB control number is 0938-1054.) These suspensions reduced the reporting burden in hours and costs.

The current ICR is a result of needed reporting enhancements involving four reporting sections. Under this ICR, Reporting Section # 5 (*Grievances*), Reporting Section # 6 (*Organization Determinations/Reconsiderations*), Reporting Section #7 (Employer Group Sponsors), and Reporting Section #12 (*Plan Oversight of Agents*) would be changed to accommodate user needs for data trending, policy development, auditing, and compliance monitoring. Reporting Section #3 (*Serious Reportable Adverse Events*) will be altered due to the availability of encounter data. Only 4 of the original 20 SRAEs (the 4 "never events") and "total surgeries" will be reported via the Part C Reporting Requirements. The remaining 19 SRAEs (hospital-acquired conditions) previously reported will be available from encounter data and will no longer be part of these Part C reporting requirements. .

 # 5 Part C Grievances

The rationale for changes to this reporting section is to achieve consistency with Part D reporting requirements and within Part C reporting requirements. This ICR would require:

1. Part C plans to report grievance data at the contract level as opposed to the (current) PBP level, consistent with Part D grievance/appeals reporting requirements.
2. Addition of six grievance categories: total grievances, total grievances with timely notification, number of expedited grievances, number of expedited grievances, with timely notification, number of grievances related to CMS issues, and number of grievances related to CMS issues with timely notification.
3. Elimination of two grievance categories: number of fraud grievances, number of fraud grievances with timely notification, number of privacy grievances, and number of privacy grievances with timely notification.
4.

The data elements to be reported under this reporting section are:

Grievance Category	**Total number of Grievances**	**Number of grievances in which timely notification was given**
Total Grievances	**(5.1)**	**(5.12)**
Number of Expedited Grievances	**(5.2)**	**(5.13)**
Enrollment/Disenrollment	**(5.3)**	**(5.14)**
Benefit Package Grievances	**(5.4)**	**(5.15)**
Access Grievances	**(5.5)**	**(5.16)**
Marketing Grievances	**(5.6)**	**(5.17)**
Customer Service Grievances	**(5.7)**	**(5.18)**
Organization determination and reconsideration process	**(5.8)**	**(5.19)**

grievances		
Quality Of Care Grievances	**(5.9)**	**(5.20)**
Grievances related to "CMS Issues"	**(5.10)**	**(5.21)**
Other Grievances	(5.11)	(5.22)

The change from plan benefit package (PBP) reporting to contract-level reporting would decrease burden. The change from reporting 22 data elements instead of 18 data elements would increase burden. By our estimate, these changes would offset each other so that there would be no net change in burden.

#6 Organization Determinations and Reconsiderations

The rationale for changes is that revising the Part C appeals and organization determination requirements as shown below will further clarify Reporting Section #6 reporting requirements for Part C plans and will allow CMS to better utilize these data for purposes of data trending, policy development, and plan-level auditing and compliance monitoring. Also, the proposed updates attempt to bring the Part C reporting requirements in line with the Part D reporting requirements, help coordinate and improve our monitoring and compliance efforts and further CMS policy development in the area of organization determinations and appeals.

Element Number	Data Elements for Organization Determinations/Reconsiderations
6.1	Total Number of Organization Determinations Made in Reporting Time Period Above
6.2	Of the Total Number of Organization Determinations in 6.1, Number Processed Timely
6.3	Number of Organization Determinations – Fully Favorable (Services)
6.4	Number of Organization Determinations – Fully Favorable (Claims)
6.5	Number of Organization Determinations – Partially Favorable (Services)
6.6	Number of Organization Determinations – Partially Favorable (Claims)
6.7	Number of Organization Determinations – Adverse (Services)
6.8	Number of Organization Determinations – Adverse (Claims)
6.9	Number of Requests for Organization Determinations - Withdrawn
6.11	Total number of Reconsiderations Made in Reporting Time Period Above
6.12	Of the Total Number of Reconsiderations in 6.11, Number Processed Timely
6.13	Number of Reconsiderations – Fully Favorable (Services)
6.14	Number of Reconsiderations – Fully Favorable (Claims)
6.15	Number of Reconsiderations – Partially Favorable (Services)
6.16	Number of Reconsiderations – Partially Favorable (Claims)
6.17	Number of Reconsiderations – Adverse (Services)
6.18	Number of Reconsiderations – Adverse (Claims)
6.19	Number of Requests for Reconsiderations - Withdrawn

6.20	Total number of reopened (revised) decisions, for any reason, in Time Period Above
	For each case that was reopened, the following information will be uploaded in a data file:
6.21	Contract Number
6.22	Plan ID
6.23	Case ID
6.24	Date of original disposition
6.25	Original disposition (Fully Favorable; Partially Favorable or Adverse)
6.26	Case level (Organization Determination or Reconsideration)
6.27	Date case was reopened
6.28	Reason(s) for reopening (Clerical Error, New and Material Evidence, or Other)
6.29	Date of reopening disposition (revised decision)
6.30	Reopening disposition (Fully Favorable; Partially Favorable or Adverse)

Increasing the number of data elements from 6 to 30 will increase the reporting burden in terms of hours and costs. Although most if not all of the new data elements are already available to health plans, we still estimate that these changes will double the previous hourly burden and cost.

 # 7 Reporting Section: Employer Group Sponsors

This change is being done to be consistent with Part D reporting. One data element, "Employer Plan Year Start Date," is being removed. This data element was seldom used. Two data elements are being added: "Is this a calendar year plan?" and "If no, provide the non-calendar year start date." This change is not expected to impact resources even though a data element is added. The reason is that the addition of the new data element will be balanced by the reduction in resources resulting from this reporting section now being consistent with Part D reporting.

 # 12 Reporting Section: Plan Oversight of Agents[1]

1 The reporting section, *Plan Oversight of Agents*, applies to the following organization types:
1876 cost plans, local Coordinated Care Plans (Local CCP), Medicare Savings Accounts (MSA), Provider Fee-For-Service plans (PFFS), and Regional Coordinated Care Plans (Regional CCP).
Sponsors of stand-alone prescription drug plans already report these data as part of the Part D reporting requirements and are, therefore, exempt from this Part C reporting section. Employer/union group plans are also exempt from this reporting section.

Sponsors are required to comply with state requests for information about the performance of licensed agents or brokers as part of a state investigation into agents' conduct. That is, plans are responsible for monitoring the conduct of their agents. While the states oversee agent licensing, CMS needs to monitor agent complaints to determine if sponsors are investigating complaints and imposing disciplinary actions as well as reporting poor conduct to the state. These are the reasons that CMS collects plan oversight of agent data.

The enhancement of the *Plan Oversight of Agents* reporting section is a result of the need to gather and analyze more granular-level data on agents/brokers who assist in the enrollment of Medicare beneficiaries into health plans. Whereas the previous data collection (prior to 2013) required only aggregate-level data, the new collection beginning in 2014 would require agent/broker specific records and beneficiary-specific records which contain information on the brokers who enrolled them. This change would result in an increase in the estimated burden in hours and costs for this reporting section.

Data Elements:

A. Contract Number.
B. Agent/Broker Type (Captive, Employed, Independent).
C. Agent/Broker Last Name.
D. Agent/Broker First Name.
E. Agent/Broker Middle Initial.
F. Agent/Broker State Licensed. For agents licensed in multiple states, complete a row for each state in which the agent is licensed.
G. Agent/Broker National Producer Number (NPN).
H. Plan Assigned Agent/Broker Identification Number.
I. Agent/Broker Current License Effective Date.
J. Agent/Broker Appointment Date.
K. aggregate, the number of Agent/Broker disciplinary actions taken in the reporting period (related to Marketing). Examples of disciplinary actions include: retraining, verbal or written warnings, suspension, termination, etc. If multiple lines are needed for an agent (licensed in more than one state) only fill out this data element for the first line. For example, if an agent has received two disciplinary actions and is licensed in Florida and Georgia, both actions should be listed under the Florida line.
L. Agent/Broker Termination Date (if applicable).
M. Termination for Cause? (Y(yes) or N (no)).
N. Third-party Marketing Organization (TMO)/Field Marketing Organization Name(FMO), if applicable.
O. The number of new enrollments in the reporting period. If more than one line is filled out because of agent being licensed in multiple states, please put enrollments in by state.

1. New Enrollments:

CMS is defining "new enrollments" for reporting purposes as new to the organization. A change from one Plan Benefit Package (PBP) to another PBP, within the same organization, is not considered "new enrollment" for purposes of these reporting requirements. In addition, Plans should report on all agents/brokers, not just independent agent/brokers. For all new enrollments (initial or renewal) during the reporting period for which an Agent/Broker is associated (includes instances where the agent/broker was assigned after the enrollment was initiated), indicate:

A. Contract Number.
B. Plan Benefit Package (PBP) Number.
C. Beneficiary Last Name.
D. Beneficiary First Name.
E. Beneficiary Middle Initial.
F. Beneficiary HICN or RRB Number.
G. Agent/Broker Last Name.
H. Agent/Broker First Name.
I. Agent/Broker Middle Initial.
J. Agent/Broker National Producer Number (NPN).
K. Plan Assigned Agent/Broker Identification Number.
L. Enrollment Mechanism. (Plan/Plan Representative Online; CMS Online Enrollment Center; Plan Call Center; 1-800-MEDICARE; Paper Application; Auto-Assigned/Facilitated; Other).
M. Enrollment Application Date.
N. Enrollment Effective Date.
O. The number of Agent/Broker complaints filed by the beneficiary in the reporting period.
P. Of the number reported in O, the number of Marketing related complaints.

#3 Serious Reportable Adverse Events (Hospital-Acquired Conditions (HACs))

Never Events (these events will be reported as previously but coding will be in ICD-10).

1. Surgery performed on the wrong body part. (140.7)
2. Surgery performed on the wrong patient. (140.8)
3. Wrong surgical procedure performed on a patient. (140.6)
4. Intraoperative or immediate death in an ASA class I patient.

A. Justification

1. Need and Legal Basis

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

Before Part C reporting, CMS had mainly clinical performance reporting sections on Part C plans such as HEDIS, CAHPS, and the Health Outcomes Survey (HOS). However, CMS also needs other performance data on MAOs under Part C Medicare. CMS receives inquiries about the beneficiary use of available services, patient safety, grievance rates, and other factors pertaining to the performance of MA plans. Prior to the collection and reporting of these data, CMS was unable to respond to these requests for information.
There are a number of information users of Part C reporting. They include central and regional office staff that uses this information to monitor health plans and to hold them accountable for their performance. Among CMS users are group managers, division managers, branch managers, account managers, and researchers. Other government agencies such as GAO and OIG have inquired about this information. Health plans can use this information to measure and benchmark their performance. CMS intends to make some of these data available for public reporting as "display measures" in 2013.

3. Use of Information Technology

MA organizations and other health plan organizations (e.g., cost plans) utilize the Health Plan Management System (HPMS) to submit or enter data for 100% of the data elements listed within these reporting requirements. CMS and its subcontractors, in turn, communicate to these organizations regarding this information, including approval and denial notices and other related announcements through HPMS. HPMS, therefore, is a familiar tool to MA organizations. 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

   Most of the Part C reporting requirements data for reporting year 2014 will be reported on an annual basis. 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 organizations within 60 days of data submission.

8. Federal Register/Outside Consultation

   The 60-day Federal Register notice published on June 21, 2013 (78 FR 37542). Comments were received. A summary of the comments and our response has been added to this PRA package.

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 regarding confidentiality.

11. Sensitive Questions

The enhanced *Plan Oversight of Agents* reporting section contains some questions that could be considered "sensitive," for example, number of complaints against specific agents/brokers, disciplinary actions, and terminations (refer to Appendix A). CMS will adhere to all statutes, regulations, and agency policies with regard to these questions.

12. Burden Estimates (Hours & Wages)

The burden associated with this ICR is the time and resources it takes to develop computer code, to "de-bug" computer code, gather the 'raw" data, "clean" the data in order to eliminate errors, enter data, to compile the data, review technical specifications, and perform tests on the data.

Anticipated staff performing the activities required of this data collection and reporting would be computer systems analysts. An average competitive hourly rate (including wages, benefits and overhead) of $64.57 was used to calculate estimated costs. The average hourly rate was based on publically-available data from the Bureau of Labor Statistics (refer to http://www.bls.gov/oes/current/oes151121.htm).

Below are the burden estimates from the 2013-2015 ICR (OMB # 0938-1054):

Annual responses = 6,715
Total hour burden=120,190
Total annual cost=$ 7,963,160

The burden annual estimates for this CY2014-CY2016 ICR are:

Annual responses = 6,715
Total hour burden = 169,558
Total annual cost=$ 10,948,360

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

The estimated annual cost is $300,000 to support reporting through the Health Plan Management System (HPMS). This is the same as previously reported.

15. Changes to Burden

There is a decrease in cost and hour burden. One measure was added and another was enhanced and there was a decrease in reporting frequency of some measures.

16. Publication/Tabulation Dates

Collection of these data will commence in January 1, 2014. 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.

B. Collections of Information Employing Statistical Methods

This information collection does not require statistical analyses to be conducted by the reporting organizations.

This is a Blank Page