U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE AND MEDICAID SERVICES

COLLECTION OF DIAGNOSTIC DATA FROM MEDICARE ADVANTAGE ORGANIZATIONS FOR RISK ADJUSTED PAYMENTS

OFFICE OF MANAGEMENT AND BUDGET
CLEARANCE PACKAGE SUPPORTING STATEMENT

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I. Background and Summary

A. History

In the Balanced Budget Act of 1997 (BBA), Congress created the Medicare+Choice (M+C or Part C) program in order to expand the types of private entities eligible to contract with Medicare and to address some perceived flaws in the risk-contracting program. Congress subsequently refined the M+C program through the Balanced Budget Refinement Act of 1999 (BBRA) and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Most recently, under the Medicare Prescription Drug Benefit, Improvement and Modernization Act of 2003 (MMA), Congress restructured the M+C program into the Medicare Advantage (MA) program and added an outpatient prescription drug benefit, Part D.

The 1997 BBA and later legislation required CMS to adjust per-beneficiary capitation payments with a risk adjustment methodology using diagnoses to measure relative risk due to health status instead of just demographic characteristics such as age, sex, and Medicaid eligibility. Risk adjustment using diagnoses provides more accurate payments for MA organizations, with higher payments for enrollees at risk for being sicker, and lower payments for enrollees predicted to be healthier.

The MMA also instituted a bidding system in Parts C and D with a significant role for risk adjustment. Thus, independent of enrollment and payment, risk adjustment now plays a significant role simply because it is central to the bidding process. Under the MMA, risk adjustment is used to standardize bids. Plans bid on the average beneficiary, referred to as a "standardized" bid for a beneficiary with a 1.0 risk score. This enables comparison of Part C and D bids against a baseline (average) standard, even though every plan will have different enrollee characteristics and benefit packages and will therefore have different costs.

Under OMB No. 0938-0878 (4/2002 – 10/2005), CMS received PRA clearance to collect inpatient and outpatient data for Part C using the CMS-HCC model.[1] In this document, CMS seeks to renew that PRA approval. The agency also seeks clearance for changes in data collection in order to fulfill new mandates under the MMA. This document focuses on the status of implementation to date including key sources of legislative authority to collect data; description of the risk adjustment models to be used for Parts C and D; their predictive power; the data collection process and requirements; ongoing interaction and collaboration with industry; and the increasing significance of data collection for risk adjustment in view of the payment methodologies established by the MMA.

B. Justification

B.1. Legal Basis and Needs

1 CMS had previously obtained PRA clearances to collect hospital inpatient and outpatient data from Managed Care organizations using different models, under OMB No. 0938-0711 and OMB No. 0938-0805.

The BBA constituted the first legislative mandate for health status risk adjustment. Section 1853 (a)(3) of the Social Security Act as enacted by Section 4001 of Subtitle A of the BBA required the Secretary to implement a risk adjustment methodology that accounted for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice (now MA) organizations. The new methodology was to be effective no later than January 1, 2000. The BBA also required that M+C organizations submit data for use in developing risk adjusted payments.

The BBA stated that for purposes of risk adjustment inpatient hospital data were to be submitted for discharges occurring after July 1, 1997, while other data (e.g., hospital outpatient and physician data) were to be submitted after July 1, 1998. No organization was required to submit data before January 1, 1998. Following passage of the BBA, CMS promulgated the Medicare+Choice Regulation (42 CFR 422). This regulation references the requirement for M+C organizations to submit outpatient as well as inpatient hospital encounter data.

In December 2000, section 603 of BIPA amended §1853(a)(3)(C) of the Act (previously amended by §511 of the BBRA) by specifying that CY 2003 payments would only be adjusted 10 percent by the new risk adjustment method. Therefore, under BIPA CMS continued to apply the transition percentages that were already in effect for CY 2000- 2002: 90 percent demographic adjustment and 10 percent risk payment.

BIPA further stipulated that the risk adjustment methodology for 2004 and succeeding years should be based on data from both inpatient hospital and ambulatory settings. BIPA also altered the risk adjustment phase-in schedule that had been set in the BBA. The new phase-in schedule for the health status aspect of risk adjustment became: in 2004, 30% health status or "risk" payment with 70% of payment still based on the demographic-only method; in 2005, 50% risk and 50% demographic payment; in 2006, 75% risk/25% demographic; and 100% risk payment in 2007. Note that the risk model includes factors for demographic characteristics of enrollees while adding health status measures; it does not eliminate demographic factors from risk adjustment. In the MMA, Congress maintained its former commitment to risk adjusted managed care payments by mandating risk adjusted payment for both Parts C and D.

CMS' fundamental goal is to have the least burdensome data submission requirements necessary for accurate payment and appropriate program oversight. We believe that diagnostic data provide the most reliable approach to ensuring that payment calculations are accurate. In the absence of these data, we would not be to accurately determine the beneficiary's health (risk) status. We further believe that our limited data set requirement minimizes the burden of data collection and management, while maintaining the accuracy of payment related calculation. Also, by focusing on a small number of critical data elements the ability of MA organizations to collect and submit accurate, timely and complete data for the purpose of payment calculations will be optimized. Our overall premise is that in order to fulfill the statutory requirements of the Act, we will need to continue to collect the diagnostic data elements listed below from MA organizations.

The following table summarizes the key functions for data collection for risk adjustment under the Social Security Act as amended by the BBA, BBRA, BIPA, and most recently the MMA.

Table 1. The Roles of Risk Adjustment and Authorizing Legislation	
Function	**Authorizing legislation (The Social Security Act)**
Risk adjusted Part C payment	§1853(a)(1)(C), 1853(a)(3)
Data Collection	§1853(a)(3)(B)
Publishing Part C risk factors	§1853(b)(1)(B)
Risk adjusted Part D payment	§1860D-15(a)(1)(A)
Data collection	§1860D-15(c)(1)(C)
Publishing Part D risk factors	§1860D-15(c)(1)(D)
Risk adjustment in Part C bidding (used in determination of benchmarks and premiums	§1854(a)(6)(A)(i) 1854(b)(3)
Risk adjustment in Part D bidding	§1860D-11(b)(2)(B)
Risk adjusted stabilization fund payments	§1858(e)(4)(B)(ii)

B.2. Information Users

Table 1 above also summarizes the purposes for which the diagnostic data will be used. CMS will use the data to make risk adjusted payment under Parts C. MA and MA-PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS-HCC and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan.

B.3. Information Technology

The risk adjustment data is collected 100% electronically. Risk adjustment data are processed through the Risk Adjustment Processing System (RAPS). A summary of the data collection/submission process are as follows.

B.3.1. Risk Adjustment Data Collection/Submission Overview

MA organizations use an electronic connection between the organization and CMS to submit risk adjustment data and to receive information in return. Submitters must sign an Electronic Data Interchange (EDI) agreement annually in advance of submission. MA organizations have a choice between three connectivity options: CONNECT:DIRECT, File Transfer Protocol (FTP) and Gentran.

Hospital inpatient, hospital outpatient, and physician risk adjustment data must be submitted at least quarterly. The International Classification of Diseases-9th Edition-Clinical Modification (ICD-9-CM) codes are 3- to 5-digit codes that provide the core of Risk Adjustment data. The ICD-9-CM codes are used to describe the clinical reason for the patient's treatment. These codes

do not describe the service performed, just the patient's medical condition. Diagnosis codes drive the risk score, which drive the risk adjustment reimbursement. For each enrollee, MA organizations may submit all the patient's valid diagnoses codes, but only the relevant codes (i.e., codes that are utilized in the risk adjustment model) will be used in the risk score computation. However, MA organizations are required to report at least once per enrollee during the data collection period. On its website, CMS provides and periodically updates a listing of the minimal ICD-9-CM codes required to group diagnoses for risk adjustment (http://www.cms.hhs.gov.MedicareAdvtgSpecRateStats/06_Risk_adjustment.asp#TopOfPage).

B.3.1.a) Data Collection

MA organizations may choose to collect data from providers in a variety of formats:
-Standard fee-for-service claim or encounter formats:

- Uniform Billing Form (UB-04)
- HCFA 1500
- National Standard Format (NSF) v3.01
- American National Standards Institute (ANSI) X12 837 v30.51 or v40.10. Health Insurance Portability and Accountability Act (HIPAA) mandated transactions must use v40.10
- Superbill
- RAPS format

B.3.1.b) Data Submission

CMS worked extensively with the industry to develop a minimum required data set for risk adjustment in order to reduce the reporting burden. The risk adjustment minimum data set contains 5 data elements:

1. Health Insurance Claim Number (HIC Number)
2. ICD-9-CM Code (Diagnosis Cluster* for Each Enrollee Diagnosis Submitted)
3. Service From Date
4. Service Through Date
5. Provider Type (hospital inpatient-principal diagnosis, hospital inpatient-other diagnoses, hospital outpatient, physician)

*Each diagnosis cluster is stored as a unique cluster associated with an enrollee's HIC number.

As of 2007, MA organizations must submit data to CMS in the RAPS format. Previously, organizations could also submit data using standard fee for service claims. Only two plans were submitting under formats other than RAPS, however. Working with CMS these two plans were able to convert to the RAPS format in two months.

The base period for submission of risk adjusted payment data is the calendar year prior to the payment year. The reporting periods (i.e., Data Submission Schedule) are:

Initial

The Initial submission deadline is the first Friday in September prior to the payment year. It represents the 12 month date of service period that extends from July 1st of a given year through June 30th of the following year. Risk adjustment payments are reset in January each year to reflect new rates and risk scores.

Mid-Year

The Mid-Year submission deadline is the first Friday in March of each payment year. It represents the calendar year dates of service period from January 1st through December 31st of the year prior to the payment year. Payments are updated each July to reflect the mid-year risk adjustment update.

Reconciliation

The Final submission deadline is the last day of January in the year following the payment year. It represents the final reconciliation data for dates of service from January 1st through December 31st of the year prior to the payment year. Final reconciled payments are made in August of the year following the payment year.

B.4. Duplication/Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. This document requests a renewal of permission to collect the hospital inpatient, hospital outpatient, and physician diagnostic data that are currently collected under the authority of OMB No. 0938-0878 and of which there is no duplicative information.

B.5. Small Business

The data submission process is designed to accommodate a wide variety of users. Thus, it maximizes advantages to the small business community by reducing the number of required data elements, providing for multiple enrollee sizes, and allowing for multiple connectivity options and submission formats.

B.6. Collection Frequent

In order for reimbursement to proceed in a timely and accurate manner while minimizing burden, CMS continues to require MA organizations to submit diagnostic data quarterly. Each quarter's submission represents approximately one quarter of the data that the organization will submit over the course of the data collection period (12 months). MA organizations are allowed the option of submitting data more frequently. There has been no change in collection frequency since the last PRA approval.

B.7. Special Circumstances

There are no special circumstances.

B.8. Federal Register/Outside Consultation

In implementing the requirements of the BBA, BIPA, and the MMA, CMS has made and continues to make a concerted effort to address issues raised by hospitals, health plans, providers, and other interested parties.

The Federal Register notice for the original Information Collection Request (ICR), CMS-4031-N, was published on December 14, 2001. In Appendix B, we document the agency's early consultation with industry. Since the last ICR in 2005, CMS has continued consultation with industry through regional training, regular user group conference calls, and a new web-based Q&A database. In these forums, summarized in Table 2, CMS discusses the continuing need for risk adjustment data submission, provides technical assistance, listens to concerns, and conducts training for stakeholders. When developing the Rx-HCC model, CMS also consulted extensively with industry, the American Academy of Actuaries, and other Departmental agencies including OMB and the Assistant Secretary for Program Evaluation (APSE).

Regional training sessions provide detailed information and instruction on the latest data collection requirements. They are designed for MA staff involved in data submission in various capacities from executive management to operations and IT systems. User group teleconferences are a forum for identification, discussion and resolution of diagnostic data submission issues related to risk adjustment. Risk adjustment user groups were conducted monthly until passage of the MMA. Currently, CMS conducts user group teleconferences weekly for questions related to risk adjustment and any other concerns as MMA implementation moves forward.

Table 2. Communication/Consultation with Industry		
Type of Consultation	**Dates**	**Status**
MA Organization-specific One-Day Site Visits to discuss data collection and data submission	Annually, March – June 1999 – present	Ongoing
MA Risk Adjustment Policy Conference Calls for the MA industry	Monthly, 2000 - 2005	Complete
Regional risk adjustment training for MA Organizations, and associated stakeholders (various sites)	July – August 2002 - 2008	Complete
Technical User Group Conference Calls for MA/MA-PD organizations	Monthly 2002 – present	Ongoing
Development of the Part D risk adjuster: Consultation with industry, topical experts, and other Departmental agencies	2004-2005	Complete
CMS Open Door Forum on Risk Adjustment	January 2005	Complete
Part D User Group Conference Calls for MA Organizations and PDPs	Weekly, January 2005 to present	Ongoing
Regional MMA technical assistance application training for MA Organizations, PDPs, and associated stakeholders (various sites)	February 2005	Complete
Technical User Group Conference Calls for actuarial issues and training in bidding	Weekly for months prior to the annual bidding deadline in June - June 2005-present	Ongoing
Bidding Conference for MA-PDs and PDPs	Annually, Spring 2005-present	Ongoing
Risk Adjustment/Payment Emailbox	2007 - present	Ongoing
Annual Advance Notice and Announcement of Payment Rates Process	Annually in February and April respectively	Ongoing

B.9. Payment/Gifts to Respondents

Filing an encounter form or claim itself does not result in payments or gifts to respondents, and many conditions must be met before risk adjusted payment is actually made. However, submitting data for risk adjustment is a condition of payment under Parts C and D.

B.10. Confidentiality

The data are protected and kept confidential under System of Record (SOR) #09-70-0005.

We also note that any electronic claims or encounter data sent from providers (hospitals and physicians) to the MA organization are HIPAA-covered transactions.

B.11. Sensitive Questions

This data collection does not require answering questions of a sensitive nature.

B.12. Burden Estimate (Wages & Hours)

The burden associated with reporting risk adjustment data depends upon two factors, the amount of data that must be reported and the percentage of data that is reported using automated vs. manual processes. The amount of data that must be reported is a function of the number of diagnoses that will be reported per beneficiary and the number of reports that will be filed per beneficiary.

On average, beneficiaries in traditional Medicare have 12 unique diagnoses reported per year. In the risk adjustment models, CMS is utilizing less than half of the diagnoses reported in traditional Medicare. If we assume that the 2,883 (CMS-HCC) and 3,194 (RxHCC) diagnoses in the models are more frequently reported than the 10,717 (CMS-HCC) and 10,406 (RxHCC) diagnoses are left out of the models, then we can safely assume that we will receive no more than one half of the number of unique diagnoses reported in traditional Medicare, or six diagnoses per beneficiary per year. A frequency distribution of the anticipated number of significant diagnoses per beneficiary per year confirms that assumption to be accurate. The table below illustrates this distribution.

Annual Significant Diagnoses per Beneficiary		
Number of Significant Diagnoses per Year	Percent of Beneficiaries	Weighted Average
0	11%	0.00
1	6%	0.06
2	8%	0.17
3	10%	0.29
4	10%	0.40
5	10%	0.48
6	9%	0.51
7	7%	0.51
8	6%	0.48
9	5%	0.44
10	4%	0.40
11	3%	0.35
12	3%	0.30
13	2%	0.26
14	2%	0.22
15	2%	0.34
16	2%	0.32
17	1%	0.13
18	1%	0.11
Total	100%	5.76

From traditional Medicare experience, we know that 11% of beneficiaries will have no significant diagnoses reported in a given year, meaning that at least 11% of MA enrollees will have no risk adjustment data reported in a year.

Based on a quarterly reporting requirement, the maximum number of submissions that an MA organization will report on a beneficiary in a reporting year will be four. The annual average number of submissions per beneficiary that we anticipate receiving is 2.23. The table below shows our assumptions.

Annual Risk Adjustment Submissions Per Beneficiary		
Submissions per year	Percent of beneficiaries	Weighted average
0	11%	0.0
1	22%	0.22
2	22%	0.45
3	22%	0.67
4	22%	0.89
Total	100%*	2.23

*Total shown may not sum due to rounding.

After calculating the weighted averages, we can derive the average number of data elements per beneficiary record. The required elements on a record are a beneficiary identifier number (HIC) followed by a series of diagnosis clusters, each cluster consisting of four data elements (diagnosis codes, service from date, service through date, and provider type). With all of the factors above taken into consideration, the average beneficiary record will consist of a HIC and six diagnosis clusters, or 25 elements per record. We estimate the time to send an electronic record to CMS is 0.0004 minutes and 2.9 minutes for a manual transaction. In 2009, CMS will have 852 active MA/MA-PD organizations, and we estimate that over 99 percent (i.e., 843) of them will be using electronic data exchange.

The estimated annual number of transactions is the product of the expected number of annual submissions per beneficiary and the number of projected enrollees in MA plans for 2009. CMS estimates that 9.909 million enrollees will be enrolled in MA plans; thus the estimated number of annual submissions is about 22.1 million.

Type of Submission	Estimated Average Processing Time (in minutes)	Estimated Annual Number of Submissions	Estimated Annual Processing Time (in hours)	Average Time Per MA Org. (in hours)
Keyed	2.9	220,971	10,680.3	1,186.7
Electronic	0.0004	21,876,099	145.8	0.173
ANNUAL TOTAL BURDEN HOURS			**10,826.1**	
AVERAGE ANNUAL DATA SUBMISSION TOTAL PER MA ORGANIZATION				1,186.873
AVERAGE ANNUAL COST PER MA ORGANIZATION @ $15.00/HOUR				$17,803.10
AVERAGE ANNUAL TIME PER BENEFICIARY (in minutes)				0.03
AVERAGE ANNUAL COST PER BENEFICIARY @$15.00/HOUR				$0.45

It should be noted that the increases in expected MA organizations' and beneficiaries' enrollments had a direct impact on the ICR's 2009 expected burden. The number of MA organizations expected for 2009 is 852 while they were 505 for 2006. The number of expected beneficiaries for 2009 is 9.909 million, but was 6.319 for 2006. Thus, the number of estimated responses for 2008 is 22 million while they were 14 million for 2005. Yet, the number of plans utilizing electronic transmissions remained constant.

B.13. Capital Costs

We do not anticipate significant start-up costs for any new MA plans submitting data. CMS further believes that the connectivity option will equalize the data submission costs regardless of enrollee size.

The capital and operational costs for this data collection that may be incurred by MA organizations should be part of their customary and reasonable business practices. Health plans must receive diagnostic data from providers in order to manage the services provided to their enrollees, so they already collect these data. In addition, the data are necessary for making risk adjusted payments in accordance with Congressional mandates.

CMS has developed a data collection approach that requires the MA organization to submit a minimal number of data elements that are readily available from the different provider settings (hospital inpatient, hospital outpatient, and physician).

B.14. Cost to Federal Government

The costs to the Federal Government for data collection can best be described as the total costs of acquiring and preparing the required data for MA organization payment calculation. Calculation of the precise costs for all processes involved in the data collection is not feasible for the purposes of the Paperwork Reduction Act without conducting a costly study. It is also difficult to disaggregate efforts and resources used for risk adjustment data collection and preparation from other MA payment processes and data collection efforts. Therefore, aggregate costs have been estimated taking into consideration programming, software, training, tapes, overhead costs, etc. CMS's total cost for implementing risk adjustment data collection is expected to be approximately $5 million.

B.15. Reported Program Changes to Burden

Our estimate of time and cost burden to submitters (B.12 in this document or #13 on the Form 83i) has increased due to increased enrollments in plans and beneficiaries.

B.16. Publication and Tabulation Dates

The purpose of this data collection is to support the development and refinement of risk adjusted rates for beneficiaries who are members of MA organizations. There only publication and tabulation dates are:

1. Annual publication of the risk adjustment factors that result from the data for plans and other interested entities in the Advance Notice of Methodological Changes for Medicare Advantage (MA) Payment Rates and the Announcement of Medicare Advantage Payment Rates (every March-April).
2. Every month, CMS issues reports to each plan containing the risk scores for the beneficiaries enrolled in their plan.

17. Expiration Date

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

18. Certification Statement

CMS has no exceptions to Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

C. Statistical Methods

CMS will not use statistical methods to collect these data. In order to make accurate payment, CMS needs to collect 100% of the relevant diagnostic data that are used in the risk adjustment models.

II. Supporting Legislation and Documents

ATTACHMENT 1
Authorizing Legislation

APPENDIX A
Early Industry Consultation

Attachment 1

Authorizing Sections of the Social Security Act of 1967 (the Act)

Sec. 1853. PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS

(a) Payments to Organizations.—

(1) Monthly payments.—

(C) Demographic adjustment, including adjustment for health status.—

(i) In general.— The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(ii)Application during phase-out of budget neutrality factor—for 2006 through 2010

(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part A and B to the extent that the Secretary has identified such differences.

(II) In order to ensure payment accuracy, the Secretary shall conduct an analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated into the risk scores only for 2008, 2009, and 2010. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available.

(3) Establishment of risk adjustment factors.—

(A) Report.—The Secretary shall develop, and submit to Congress by not later than March 1, 1999, a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status. Such report shall include an evaluation of such method by an outside, independent actuary of the actuarial soundness of the proposal.

(B) Data collection.—In order to carry out this paragraph, the Secretary shall require Medicare+Choice organizations (and eligible organizations with risk–sharing contracts under section 1876) to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary

deems necessary for periods beginning on or after July 1, 1998. The Secretary may not require an organization to submit such data before January 1, 1998.

(C) Initial implementation.—

(i) In general.—The Secretary shall first provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payments by no later than January 1, 2000.

(ii) Phase-in.—Except as provided in clause (iv), such risk adjustment methodology shall be implemented in a phased–in manner so that the methodology insofar as it makes adjustments to capitation rates for health status applies to—

(I) 10 percent of 1/ 12 of the annual Medicare+Choice capitation rate in 2000 and each succeeding year through 2003;

(II) 30 percent of such capitation rate in 2004;

(III) 50 percent of such capitation rate in 2005;

(IV) 75 percent of such capitation rate in 2006; and

(V) 100 percent of such capitation rate in 2007 and succeeding years.

(iii) Data for risk adjustment methodology.—Such risk adjustment methodology for 2004 and each succeeding year, shall be based on data from inpatient hospital and ambulatory settings.

(iv) Full implementation of risk adjustment for congestive heart failure enrollees for 2001.—

(I) Exemption from phase–in.—Subject to subclause (II), the Secretary shall fully implement the risk adjustment methodology described in clause (i) with respect to each individual who has had a qualifying congestive heart failure inpatient diagnosis (as determined by the Secretary under such risk adjustment methodology) during the period beginning on July 1, 1999, and ending on June 30, 2000, and who is enrolled in a coordinated care plan that is the only coordinated care plan offered on January 1, 2001, in the service area of the individual.

(II) Period of application.—Subclause (I) shall only apply during the 1–year period beginning on January 1, 2001.

(b) Annual announcement of payment rates.—

(1) Annual announcement.—The Secretary shall annually determine, and shall announce (in a manner intended to provide notice to interested parties) for years before 2004 and after 2005 not later than March 1 before the calendar year concerned and for 2004 and 2005 not later than the second Monday in May before the respective calendar year—

(A) the annual Medicare+Choice capitation rate for each Medicare+Choice payment area for the year, and

(B) the risk and other factors to be used in adjusting such rates under subsection (a)(1)(A) of this section for payments for months in that year.

(2) Advance notice of methodological changes.—At least 45 days before making the announcement under paragraph (1) for a year, the Secretary shall provide for notice to Medicare+Choice organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

Sec. 1860D-15. SUBSIDIES FOR PART D ELIGIBLE INDIVIDUALS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

(a) Subsidy Payment.—In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA-PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA-PD plan of the following subsidies in accordance with this section:

(1) Direct subsidy.—A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA-PD plan for a month equal to—

(A) the amount of the plan's standardized bid amount (as defined in section 1860D-13(a)(5)), adjusted under subsection (c)(1), reduced by

(c) Adjustments Relating To Bids.—

(1) Health status risk adjustment.—

(A) Establishment of risk adjustors.—The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) Considerations.—In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1853(a)(3) to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(C) Data collection.—In order to carry out this paragraph, the Secretary shall require—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) Publication.—At the time of publication of risk adjustment factors under section 1853(b)(1)(B)(i)(II), the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

§ 1854. PREMIUMS AND PREMIUM AMOUNTS

(a) Submission of Proposed Premiums, Bid Amounts, and Related Information.—

(6) Submission of bid amounts by ma organizations beginning in 2006.—

(A) Information to be submitted.—For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this subparagraph is as follows:

(i) The monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements (as used for purposes of section 1302(8) of the Public Health Service Act) in the payment area for an enrollee with a national average risk profile for the factors described in section 1853(a)(1)(C) (as specified by the Secretary).

(b) Monthly premium charged.—

(3) Computation of average per capita monthly savings for local plans.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA local plan and year is computed as follows:

(A) Determination of statewide average risk adjustment for local plans.—

(i) In general.—Subject to clause (iii), the Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each State, the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that State for MA local plans.

(ii) Treatment of states for first year in which local plan offered.—In the case of a State in which no MA local plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable States or applied on a national basis. (iii) Authority to determine risk adjustment for areas other than states.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than States or on a plan-specific basis.

(B) Determination of risk adjusted benchmark and risk-adjusted bid for local plans.—For each MA plan offered in a local area in a State, the Secretary shall—

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(1)) for the area by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non- drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings.—The average per capita monthly savings described in this subparagraph for an MA local plan is equal to the amount (if any) by which—

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(4) Computation of average per capita monthly savings for regional plans.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA regional plan and year is computed as follows:

(A) Determination of region wide average risk adjustment for regional plans.—

(i) In general.—The Secretary shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006) for each MA region the average of the risk adjustment factors to be applied under section 1853(a)(1)(C) to payment for enrollees in that region for MA regional plans.

(ii) Treatment of regions for first year in which regional plan offered.—In the case of an MA region in which no MA regional plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable regions or applied on a national basis.

(iii) Authority to determine risk adjustment for areas other than regions.—The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than MA regions or on a plan-specific basis.

(B) Determination of risk-adjusted benchmark and risk-adjusted bid for regional plans.—For each MA regional plan offered in a region, the Secretary shall-

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1853(j)(2)) for the region by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non- drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings.—The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which—

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)

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(b) Submission of BIDS, Premiums, and Related Information.—

(2) Information described.—The information described in this paragraph is information on the following:

(B) Actuarial value.—The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1860D-15(c)(1)(A) (as specified by the Secretary).

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(e) Stabilization Fund.—

(4) Plan retention funding.—

(B) Payment increase.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, that does not exceed the greater of—

(ii) such amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

(I) such additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) for the region and year, to the adjusted average per capita cost for the region and year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment; being equal to

(II) the weighted average of such benchmark amounts for all the regions and such year, to the average per capita cost for the United States and such year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment.

APPENDIX A

EARLY INDUSTRY CONSULTATION

Early Industry Consultation

In this appendix, we document the extensive consultation between CMS and the industry between 1997 when the BBA first mandated risk adjustment and the PRA approval in 2002. Even though CMS documented this material in the last PRA's Supporting Documentation, we append it here again because we believe it is important to not only document communication with industry since the last data collection approval but also to provide a listing of the agency's efforts since the beginning of policy implementation.

Beginning in 1997, CMS communicated with the M+C (now MA) industry on a continuous, frequent basis using many different forums including the creation of technical user groups and regional training. The agency held discussions with key industry organizations such as: the American Association of Health Plans (AAHP), the Health Insurance Association of America (HIAA), the American Hospital Association (AHA), and the Blue Cross Blue Shield Association (BCBSA); Medicaid directors; the American Medical Association and specialty societies; the National Program for All-Inclusive Care for the Elderly (PACE) Association; the Practicing Physicians Advisory Committee (PPAC); and other interested parties. CMS staff also presented at large national meetings, professional society subgroups, and the Medicare Payment Advisory Commission (MedPAC). Staff presented alternative data collection plans and listened to industry concerns, responding with revised approaches to data collection as much as possible.

We have divided the history into two sections:

- A table summarizing major forums held from 1997-2002, divided into the time periods before and after the temporary suspension of ambulatory data collection in May 2001;
- A list of key industry concerns and CMS responses when collection of ambulatory data was reinstated in 2002 using new methods that would feed data into the CMS-HCC model for 2004 payment; and

Major Forums, 1997-2002

National training sessions were held to provide the latest data collection information in overview format designed for executive level M+C organization staff. Regional training sessions were, and continue to be, designed for M+C organization technical staff responsible for collection and submission of diagnostic data to CMS. Technical user groups were designed to provide a forum for identification, discussion, and resolution of diagnostic data submission issues related to risk adjustment. User groups were conducted monthly via teleconference. In addition, a public meeting was held on January 16, 2002 at CMS headquarters in Baltimore to provide M+C organizations, providers, practitioners, and other interested parties an opportunity to ask questions and provide comments regarding the risk adjustment model selection for 2004 implementation.

The following table is divided into the period leading up to the suspension of ambulatory data collection (1997 – mid-2001) and the ensuing period leading up to its reinstatement under

revised methods (mid-2001 – mid-2002).

Industry Consultation October 1997 - May 25 2001		
Type of Consultation	**Dates**	**Status**
Preliminary Discussions on Data Collection Approach and Risk Adjustment Methodology	October-December 1997	Complete
Monthly Conference Calls with Plans and Industry Associations (AAHP, HIAA, BCBSA, other)	Began July 1999	Complete
Public Meetings	March 1998; November 1999	Complete
Special Training (e.g. with FIs)	April 1998	Complete
National Training for M+C Organizations (at CMS Central Office)	March 2000; June 2000; September 2000	Complete
Regional Training for M+C Organizations (various sites)	June 2000; July 2000; September 2000; October 2000	Complete
Regional Risk Adjustment Training for Physicians (various sites)	August 2000; September 2000; November 2000	Complete
Technical User Groups	October-December 2000; January-May 2001	Complete
M+C Organization-Specific One-Day Site Visits to Discuss Data Collection and Data Submission	March-April 1999; May-June 2000; April-May 2001	Complete
Industry Consultation June 2001 – July 2002		
Type of Consultation	**Dates**	**Status**
Monthly Conference Calls with Plans and Industry Associations (AAHP, HIAA, BCBSA, other)	Began July 1999	Complete
Special Discussions with M+C Organizations and Industry Associations on Ambulatory Data Collection and Risk Adjustment Models	June-December 2001	Complete
Special Discussions with M+C Organizations on new Risk Adjustment Processing System (RAPS) Format and Data Submission	January-March 2002	Complete
Special Discussions with M+C Organizations on Physician Training Needs	February-March 2002	Complete
Public Meetings	January 2002	Complete
Regional Training for M+C Organizations (various sites)	June 2002	Complete
Technical User Groups	August 2001-July 2002	Complete
M+C Organization-Specific One-Day Site Visits to Discuss Data Collection and Data Submission	May-June 2001; March-May 2002	Complete

Key Concerns and Agency Response, 2001-2002

Beginning with the January 15, 1999 announcement of the PIP-DCG methodology, CMS announced its intention to implement a comprehensive risk adjustment method and began an intensive, iterative process of consultation with the industry. In January 2000, Medicare

implemented risk adjusted payments to M+C organizations basing payments in part on diagnostic information from inpatient hospital discharges. The inpatient hospital risk adjuster (PIP-DCG) was viewed as an initial step in the implementation of a more accurate risk adjustment methodology that would incorporate diagnoses received from ambulatory settings.

CMS initially implemented an encounter-based data collection system. This approach required M+C organizations to electronically submit a record of each service provided to each enrollee using standard (but abbreviated) Medicare reporting formats. Because of concerns over the burden of collecting ambulatory encounter data, CMS temporarily suspended the collection of these data on May 25, 2001 through June 30, 2002. However, BIPA still required CMS to incorporate ambulatory data with inpatient data for January 2004 risk adjusted payment. Therefore, CMS developed an improved risk adjustment methodology that incorporated ambulatory data with inpatient data while reducing data collection burden.

Summary of concerns

Primary concerns were:

- The data collection system was based on all encounters received from hospital inpatient, hospital outpatient, and physician settings.
- The submission requirements were based on Medicare fee-for-service (FFS) claims formats.
- The formats were required based on the need to perform all edits within Medicare claims processing systems.
- M+C organizations were required to submit data, such as the Unique Physician Identification Number (UPIN), type of bill, procedure codes, and other data for model maintenance and data verification. These and other data elements were edited and caused rejections even though they were not required for risk adjustment payment.

Summary of Response

In response to these concerns, CMS began to redefine radically the data collection and data submission process used for risk adjustment. First, after discussions with interested parties, CMS transformed the approach originally used (encounter-based reporting) to data reporting for purposes of calculating risk adjustment factors and payments only. This approach allowed CMS to reduce drastically the requirements for the amount of data submitted, the data formats used, and the data processing systems that would be utilized. CMS also decided to only require M+C organizations to submit the diagnoses required to make accurate risk adjustment payments. These two decisions allowed CMS to develop a new, more flexible and less burdensome data collection strategy and processing system. A number of other parameters of the approach were redesigned as well.

Detailed Listing

The following section provides detailed descriptions of how CMS addressed the primary concerns of M+C organizations and made substantial changes to risk adjustment data collection, data submission, and data processing.

1. Data collection for risk adjusted payments was based on all encounters received from hospital inpatient, hospital outpatient and physician settings.

CMS RESPONSE

The requirements for data collection previously established required that all encounters from the hospital inpatient, hospital outpatient, and physician settings were to be submitted by M+C organizations on a monthly basis, at a minimum. CMS addressed this issue by requiring quarterly submissions based on a 12-month data collection period. Also, M+C organizations were only required to submit each beneficiary-specific diagnosis once during a data collection period regardless of service setting. However, CMS allowed diagnoses to be submitted more frequently if the M+C organization wished to submit diagnoses based on number of encounters received.

2. The submission requirements were based on Medicare FFS claims formats.

CMS RESPONSE

The previous data submission method necessitated the exclusive use of Medicare FFS claims formats such as the UB-92 (v6.0), ANSI X12 837 (v3051 or v4010), NSF (v3.0). Smaller plans were allowed to use a Medicare FFS-based software package, PC-ACE, to generate a Medicare FFS compliant form.

CMS addressed the data submission issue by allowing flexibility in use of submission formats. CMS developed the Risk Adjustment Processing System (RAPS) format specifically for M+C organizations and the collection of data for risk adjustment. This format requires M+C organizations to provide only the data required for risk adjustment by implementing a non-traditional format. Moreover, M+C organizations could use superbills to collect data for risk adjustment on periodic or encounter bases. M+C organizations could then submit these data via the RAPS format.

Specifically, CMS examined the data submission formats required for system processing and made changes to allow M+C organizations more flexibility in choice of submission format. With RAPS, M+C organization data submission to CMS could be accomplished by one or more of the following methods:

1) full or abbreviated UB-92 Version 6.0
2) full or abbreviated National Standard Format (NSF) Version 3.0
3) ANSI X12 837 Version 30.51 (only for those submitters currently utilizing this version)
4) ANSI X12 837 Version 40.10
5) the new Risk Adjustment Processing System (RAPS) format
6) on-line direct data entry (DDE)

These changes allowed M+C organizations a number of options for submission and did not require one type of submission format. That is, each M+C organization could select the most efficient method for data submission, taking into account the unique nature of its data systems. M+C organizations could elect to utilize more than one submission method. All transactions were submitted using the same network connectivity that M+C organizations currently utilize for

hospital inpatient data submission.

Regardless of the method of submission that a M+C organization selected, all transactions were made subject to the same edits. The Front-End Risk Adjustment System (FERAS) now automatically formated all DDE transactions into RAPS format. Transactions submitted in claim or encounter formats were converted to the RAPS format prior to system editing.

3. The Medicare FFS claims format necessitated the use of Medicare FFS claims processing systems.

CMS RESPONSE

Originally, CMS chose to utilize existing Medicare FFS standard processing systems to process and edit the incoming risk adjustment data. This approach to handling data became extremely burdensome to M+C organizations that were not accustomed to Medicare FFS processing systems and were not collecting many of the data elements needed to pass system edits. As mentioned above, in order to adequately address this issue, CMS created the RAPS format and processing system.

This system requires fewer data elements. The required RAPS format data elements are:

- Health Insurance Claim (HIC) Number
- Provider Type (hospital inpatient-principal diagnosis, hospital inpatient-other diagnoses, physician, and hospital outpatient)
- Service From Date
- Service Through Date
- Diagnosis Code(s)

This step eliminated all data elements that were not required to run the risk adjustment model, such as Unique Physician Identification Number (UPIN), procedure codes, and type of bill.

4. M+C organizations were required to submit additional data (e.g., UPIN, procedure codes, etc.) that were not required in running the risk adjustment models (current—PIP-DCG model and proposed—site neutral model). The additional data elements were edited and caused risk adjustment data to be rejected even though these data elements were not required for the risk adjustment model.

CMS RESPONSE

As discussed in issue #3 above, in order for the previous data processing approach employed by CMS to work, M+C organizations were required to submit data elements that were irrelevant for risk adjusted payments. Data elements such as UPINs and procedure codes were required for successful data processing. The data elements had to be valid and in the correct format for processing in the Medicare FFS systems. These data elements were cumbersome for the M+C organizations to collect and maintain and could delay submission and successful processing of data that was necessary for risk adjustment payment.

The number of edits required for the new processing system (RAPS) was drastically reduced from the number of edits required for the Medicare FFS processing systems that were employed for the previous ambulatory data collection. The number of edits was reduced from over 1,000 for all Medicare FFS processing systems to approximately 25 for the new RAPS system.